

- 
- (54) WOUND DRAINAGE DEVICE  
(75) RICHARD CHRISTIAN WRIGHT  
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(57) Claim

1. A surgical suction device comprising a drainage bag having flexible side walls to permit the bag to be rolled-up into an inoperative position and unrolled into an operative position, a body of resilient material disposed within the bag and adapted to be compressed when the bag is rolled-up into an inoperative position, an inlet port in the bag adapted for connection to a drainage tube, and releasable retaining means for retaining the bag in the inoperative position, wherein the body of the resilient material is adapted to expand when the bag is released from the inoperative position so as to cause the side walls of the bag to move apart and thereby develop at least a partial vacuum within the bag.

87770/81

APPLICATION FOR A STANDARD PATENT  
OR A STANDARD PATENT OF ADDITION

COMPLETE AFTER PROVISIONAL SPECIFICATION No. 87770/81

I, RICHARD CHRISTIAN WRIGHTof 52, VALLEYVIEW ROAD, ROLEYSTONE, W.A. 6111hereby apply for the grant of a <sup>standard patent</sup>~~patent of addition~~ for an invention entitled A DISPOSABLE SURGICALSUCTION DEVICE FOR FACILITATING THE DRAINAGE OF FLUIDS FROM  
OPERATION SITES, WOUNDS AND BODY CAVITIESwhich is described in the accompanying <sup>provisional</sup>~~complete~~ specification.~~\*(To be included in the case of a Convention application)~~

Details of basic application(s) -

Number of basic application

Name of Convention country in which basic application was filed

Date of basic application

\*(To be included in the case of an application made by virtue of section 51)

Number of original application

Person by whom made

ALLOWED

\*(To be included in the case of an application for a patent of addition)

I request that the patent may be granted as a patent of addition to the patent applied for on Application

No. Patent No.

in the name of

I request that the term of the patent of addition be the same as that for the main invention or so much of

the patent for the main invention as is unexpired.

My address for service is 52 VALLEYVIEW ROAD, ROLEYSTONE,  
W.A. 6111Dated this SEVENTH day of AUGUST 19 81

To:

THE COMMISSIONER OF PATENTS

This form must be accompanied by either a provisional specification (Form 9 and true copy) or by a complete specification (Form 10 and true copy).

\* These sections are to be completed only where applicable..

AUSTRALIA  
Patents Act 1952

87770/82

DECLARATION IN SUPPORT OF AN APPLICATION FOR A PATENT

In support of the Application made by RICHARD CHRISTIAN WRIGHT

for a patent for an invention entitled A DISPOSABLE SURGICAL SUCTION  
DEVICE FOR FACILITATING THE DRAINAGE OF FLUIDS FROM  
OPERATION SITES, WOUNDS AND BODY CAVITIES.

I, RICHARD CHRISTIAN WRIGHT  
of 52 VALLEYVIEW ROAD, ROLEYSTONE, W.A.

do solemnly and sincerely declare as follows:-

1. I am the applicant for the patent.

~~(or, in the case of an application by a body corporate,~~

~~1. I am authorized by~~

~~the applicant for the patent to make this declaration on its behalf~~

2. I am the actual inventor of the invention.

~~(or, where a person other than the inventor is the applicant)~~

~~2.~~

of

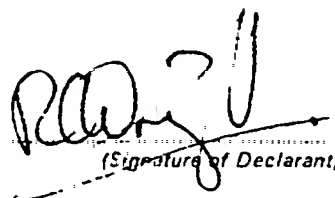
~~is the actual inventor of the invention and the~~

~~facts upon which I am entitled to make the application are as follows:-~~  
the

Declared at ROLEYSTONE this SEVENTH day of AUGUST 1981

TO

THE COMMISSIONER OF PATENTS.

  
(Signature of Declarant)

(IMPORTANT - Cross out inapplicable words in the above Form.)

# COMPLETE SPECIFICATION

(ORIGINAL)

**FOR OFFICE USE**

Application Number: PF0101  
Lodged: 07/08/81

## Class

## Int. Class

87770.82

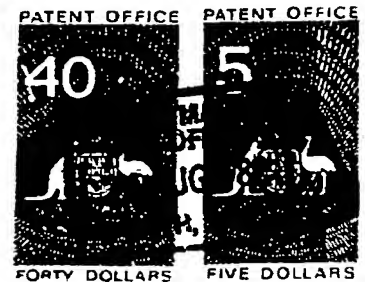
**Complete Specification—Lodged:**

**Accepted:**

**Published:**

**Priority :**

**Related Art:**



TO BE COMPLETED BY APPLICANT

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**Complete Specification for the invention entitled:** "SURGICAL SUCTION  
DEVICE"

The following statement is a full description of this invention, including the best method of performing it known to me :-

THIS INVENTION relates to a surgical suction device for evacuating fluids from the body of a patient.

10 The accumulation of tissue fluids and blood may interfere with the proper healing of a wound. To reduce this problem, it is a common medical practice to evacuate the tissue fluids and blood from the site of the wound by means of a wound suction system. A typical wound suction system comprises an evacuator in which a region of at least partial vacuum is created. A drainage tube is installed in the vicinity of the wound and coupled to the evacuator by way of a connector tube. The partial vacuum in the evacuator draws tissue fluid, blood and debris from the vicinity of the wound so as to promote proper healing. In one common type of wound suction system, the evacuator comprises a vacuum bottle in which a partial vacuum may be created by means of a manometric stopper. In another type of wound suction system, the evacuator comprises an evacuation chamber having one wall thereof movable between extended and retracted positions and biased towards the extended position. Fluid is expelled from the evacuation chamber on movement of the movable wall to the retracted position and at least a partial vacuum is developed in the evacuation chamber as the wall returns to its extended position.

It is an object of this invention to provide a surgical suction device which is of simpler construction and which is less expensive to produce than the devices referred to hereinbefore.

30 In one form the invention resides in a surgical suction device comprising a drainage bag having flexible side walls to permit the bag to be rolled-up into an inoperative position and unrolled into an operative position, a body of resilient material disposed within the bag and adapted to be compressed when the bag is rolled-up into the inoperative position, an inlet port in the bag adapted

for connection to a drainage tube, and releasable retaining means for retaining the bag in the inoperative position, wherein the body of resilient material is adapted to expand when the bag is released from the inoperative position so as to cause the side walls of the bag to move apart and thereby develop at least a partial vacuum within the bag.

10 The invention will be better understood by reference to the following description of one specific embodiment thereof as shown in the accompanying drawings in which:

Figure 1 is a schematic perspective view of a surgical suction device according to the embodiment:

Figure 2 is a schematic perspective view of the drainage bag rolled-up into the inoperative position:

Figure 3 is a schematic perspective view of the drainage bag unrolled into the operative position: and

Figure 4 is a sectional elevational view on the line 4-4 of Figure 3.

20 Referring to the drawings, the surgical suction device comprises a bag 11 the side walls 13 of which are formed of transparent flexible material. The bag is fitted with an inlet port 15; apart from the inlet port 15 the bag, is hermetically sealed. The inlet port 15 is defined by an inlet tube 17 located at one end of the bag. The inlet tube 17 is preferably fitted with a one-way valve 19 which permits fluid flow into, but not fluid flow out of, the bag. In the illustrated arrangement the one-way valve is in the form of a flutter valve fitted onto the inner end of the inlet tube 17.

30 Because of the flexible nature of the side walls 13, the bag 11 may be rolled-up, from its end opposite the inlet tube 17, into an inoperative position (as shown in Figure 2) and unrolled into an operative position (as shown in

Figures 1, 3 and 4). A releasable retaining means 21 is provided to selectively retain the bag in the inoperative position. In the illustrated arrangement, the retaining means comprises one or more strips of adhesive tape extending between the outer end of the bag and the adjacent portion of the exposed wall of the bag.

10 A body of resilient material 23, such as foamed polyurethane or other sponge-like material, is located within the bag. The resilient material preferably is absorbent, as is the case with foamed polyurethane.

In the illustrated arrangement, the body of resilient material 23 is substantially rectangular in both plan and elevation. It should be appreciated, however, that the body may be of any appropriate configuration. In addition the body may be of unitary nature, as is the case with the present embodiment, or may be in the form of a plurality of pieces of resilient material.

20 The body of resilient material 23 is adapted to be compressed when the bag is rolled-up into the inoperative position. Air is expelled from the bag either prior to or during the action of rolling-up the bag to permit the body of resilient material 23 to be tightly compressed as the bag is rolled-up. In the case where the air is expelled prior to the valve being rolled-up, this procedure would preferably be carried out during the manufacturing stage after insertion of the body of resilient material into the bag. In the case where air is expelled by the action of the bag being rolled-up, it is necessary that means be provided to permit the egress of air.

30 The inlet tube 17 is connectable to a conventional drainage tube 25 by means of a connecting tube 27.

To drain tissue fluids and blood from the region of a wound to promote healing, a surgeon installs the drainage tube 25 in the conventional manner in the vicinity of the

wound. The exposed end of the drainage tube is coupled to the bag 11 by means of the connecting tube 27. When suction is to be applied, the retaining means 21 is released to permit the bag to be unrolled. This in turn permits the body of resilient material to expand and thereby cause the side walls 13 to move outwardly with respect to each other. In this way, a reduced pressure is developed in the bag and the resultant suction induces tissue fluids, blood and debris at the wound site to flow into the drainage tube 25 and ultimately discharge into the drainage bag 11. Because of its absorbent nature, the body of resilient material 23 is able to take-up a portion of the evacuated fluid so increasing the volume of fluid which the bag may hold.

When the drainage bag is full, or no longer required, it may be discarded.

It is a simple procedure to replace a full bag with a fresh one, it merely being necessary to detach the full bag from the connecting tube 27 and install the fresh one.

It should be appreciated that the suction device according to the invention may also be used to evacuate fluids from body cavities.

Furthermore, it should be appreciated that the scope of the invention is not limited to the scope of the embodiment described. For example the drainage bag may be provided with a outlet valve whereby the contents of the bag may be emptied to permit the bag to be reused rather than replaced. The outlet valve is normally closed. When the drainage bag is to be emptied, the valve is opened to permit the contents of the bag to be discharged. With the valve open the bag is then rolled-up to displace any air inside and recompress the body of resilient material. With the bag rolled-up, the outlet valve is closed and the suction device ready for reuse. This procedure may be carried out while the suction device remains attached to the patient.

THE CLAIMS defining the invention are as follows:

1. A surgical suction device comprising a drainage bag having flexible side walls to permit the bag to be rolled-up into an inoperative position and unrolled into an operative position, a body of resilient material disposed within the bag and adapted to be compressed when the bag is rolled-up into an inoperative position, an inlet port in the bag adapted for connection to a drainage tube, and releasable retaining means for retaining the bag in the inoperative position, wherein the body of the resilient material is adapted to expand when the bag is released from the inoperative position so as to cause the side walls of the bag to move apart and thereby develop at least a partial vacuum within the bag.
2. A surgical suction device as claimed in claim 1 wherein the resilient material is absorbent.
3. A surgical suction device as claimed in claim 1 wherein the resilient material is formed of a foam-like sponge-like material.
4. A surgical suction device as claimed in claim 1, 2 or 3 wherein the body of resilient material is a unitary body.
5. A surgical suction device as claimed in claim 1, 2 or 3 wherein the body of resilient material comprises a plurality of pieces of resilient material.
6. A surgical suction device as claimed in any one of the preceding claims wherein the inlet port is provided with a non-return valve.
7. A surgical suction device as claimed in any one of the preceding claims wherein the inlet port is defined by an inlet tube provided at one end of the bag.

8. A surgical suction device as claimed in any one of the preceding claims wherein the releasable retaining means comprises one or more strips of adhesive tape adhesively bonded between the outer end of the bag and the adjacent portion of the exposed wall of the bag.

9. A surgical suction device substantially as herein-described with reference to the accompanying drawings.

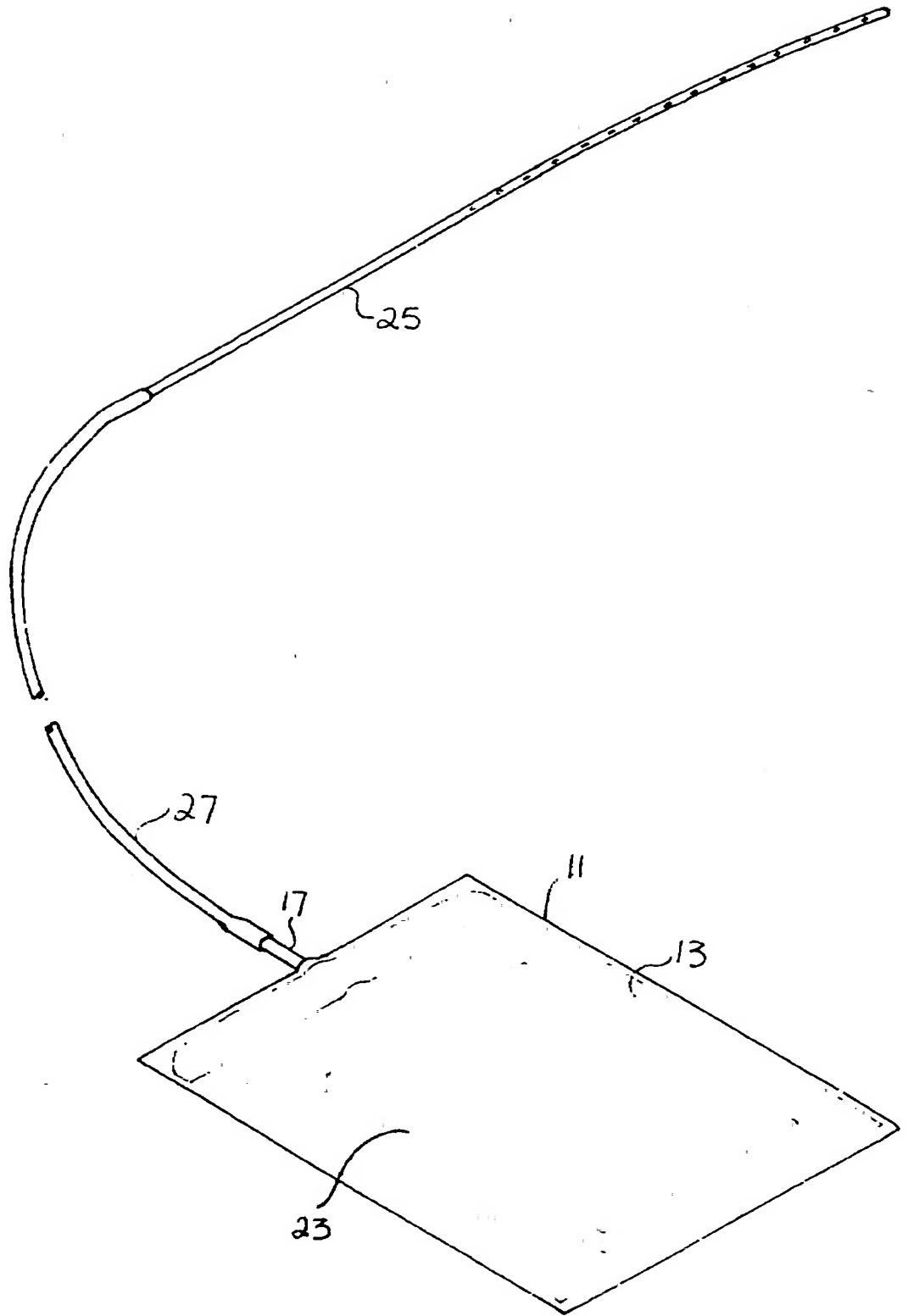
DATED this TWENTY SIXTH day of AUGUST 1982.

RICHARD CHRISTIAN WRIGHT

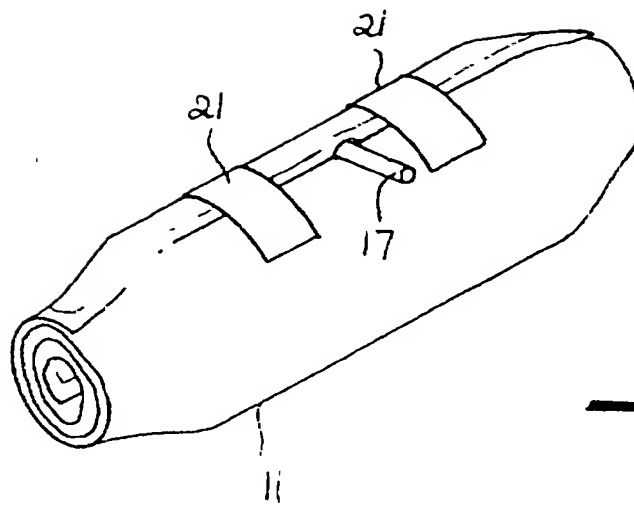
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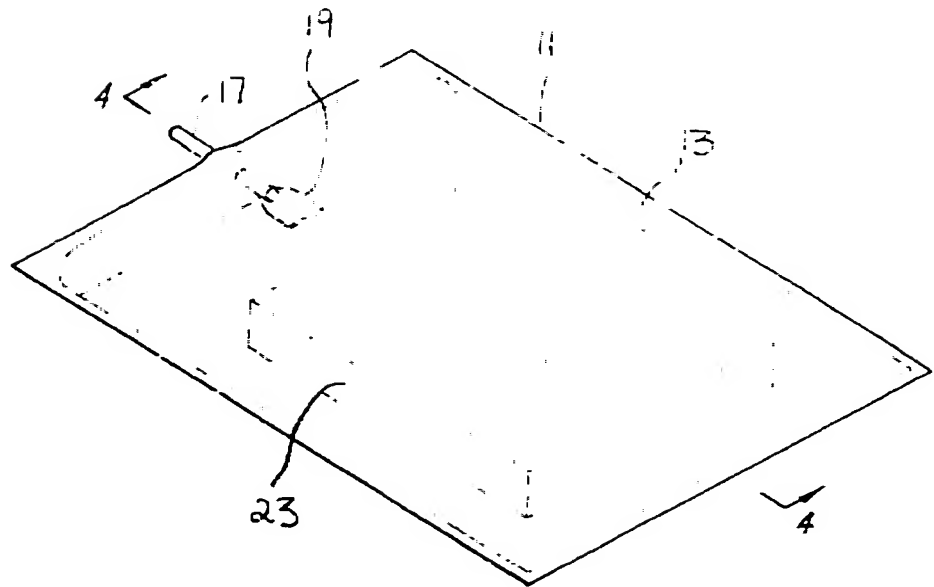
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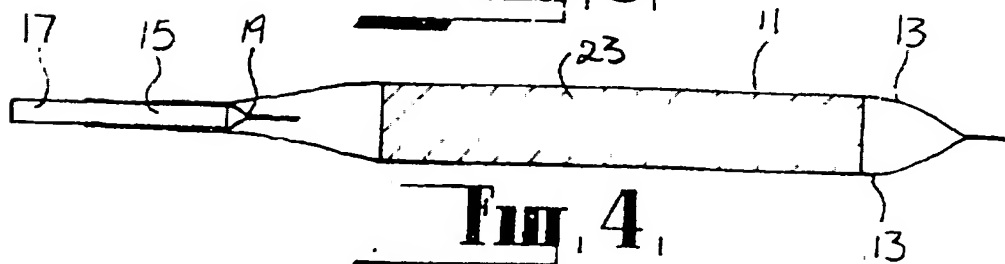
**Fig. 1.**



**Fig. 2,**



**Fig. 3,**



**Fig. 4,**

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**Surgical drape and suction head for wound treatment**

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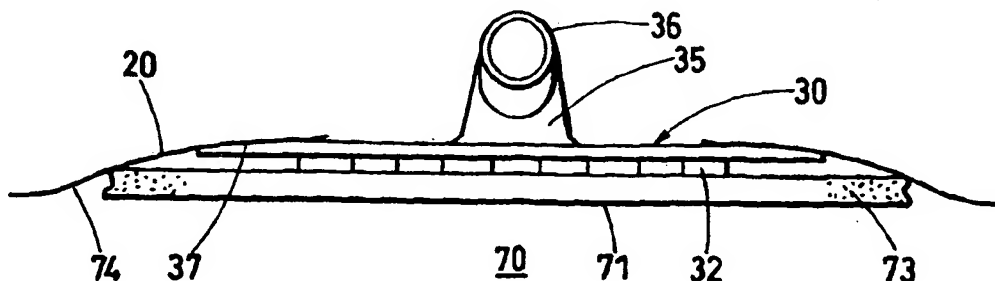
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(54) Title: SURGICAL DRAPE AND SUCTION HEAD FOR WOUND TREATMENT



(57) Abstract

This invention relates to surgical drapes and in particular provides a drape and suction head combination for attaching the suction head to a wound area. The suction head comprises a planar flange portion and a tubular connector piece on a first face which communicates with an aperture extending to the second face. The second face is formed with projections which define flow channels for facilitating flow of liquids to the aperture.

Surgical Drape and Suction Head for Wound Treatment

This invention relates to surgical drapes and suction heads for wound treatment.

Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are  
5 transparent and translucent. Typically, they consist of a flexible, plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

A further, recently developed use is for connecting a suction tube to a wound for  
10 the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible, plastics film is facilitated. For example, US Patent No. 5,437,622, describes a surgical drape which is a laminate of three materials. The first  
15 material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive coated film is strengthened with a reinforcing layer of a less flexible, plastics film. Handling bars or strips are attached to the flexible, plastics film at its lateral edges to facilitate handling of the flexible, plastics film after stripping away the protective releasable layer.  
20 Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose.



It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

According to a first aspect of the present invention there is provided a suction head for applying suction to a wound area which comprises a generally planar flange portion  
5 and a tubular connector piece on a first face for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels for facilitating flow of fluids to said aperture.

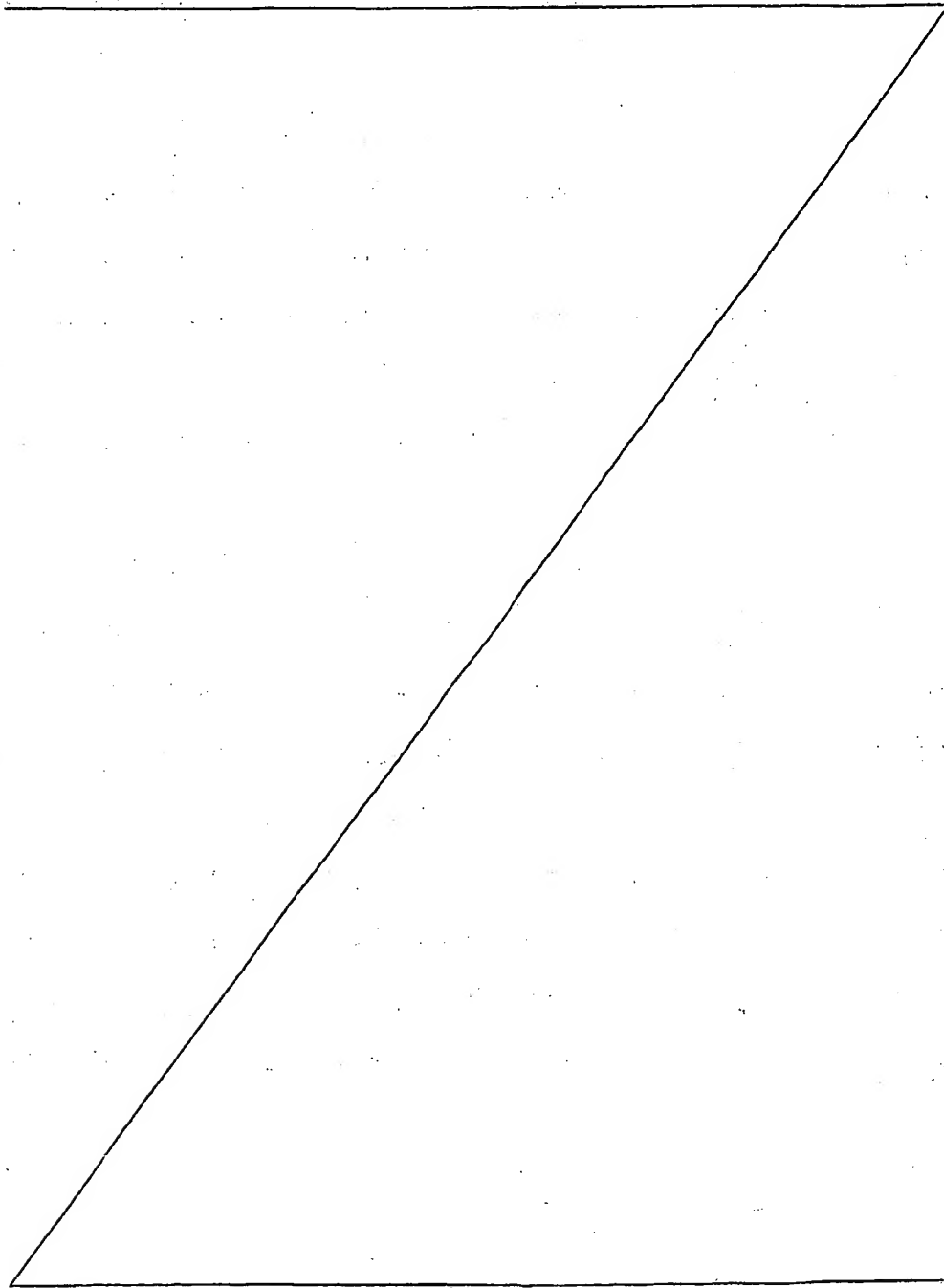
Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an  
10 inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

According to another aspect of the present invention there is provided a surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a  
15 plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer, and  
20 wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.



substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film



from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling characteristics are substantially improved by providing a protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

In a preferred form of the invention in which negative pressure therapy is applied to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. Thus, in this embodiment, the suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape affixed to the patient's skin. In this way, the suction head is held firmly in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

The invention also includes a suction head having a design which facilitates the suction of fluid from a wound area.

According to a further feature of the invention, therefore, there is provided a suction head for applying suction to a wound area which comprises a generally planar

flange portion and a tubular connector piece on a first face, for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels facilitating flow of fluid towards said aperture.

Preferably, the suction head described above is combined with a surgical drape, the  
5 drape comprising a thin, flexible, adhesive-coated plastics film, and the tubular connector piece extends through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the  
10 suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open  
15 face of the foam pad and the drape applied over the suction head to fix the assembly to the patient's skin.

Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound.  
20 These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Referring to the accompanying drawings:



Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)~9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus,

by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein, the disclosure of which is incorporated herein.

Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

In the embodiments shown in Figures 3 and 4, the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the patient's skin with the peripheral areas of exposed adhesive-coated film.

An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31. The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then be fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may

be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

5        Figures 8 and 9(a)-(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam pad, the drape being adhered to the  
10 skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c)). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in  
15 Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

Although the invention has been described with reference to specific examples it will be appreciated to those skilled in the art that the invention may be embodied in many other forms.



## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A suction head for applying suction to a wound area which comprises a  
5 generally planar flange portion and a tubular connector piece on a first face for  
connecting a suction tube to an aperture through the flange portion to the other face, said  
other face having projections defining flow channels for facilitating flow of fluids to said  
aperture.
2. A suction head as claimed in claim 1 which is combined with a surgical  
10 drape, the drape comprising a thin, flexible adhesive-coated plastics film, the tubular  
connector piece extending through an opening in the plastics film with the adhesive  
coating adhered to said first face of the flange portion.
3. A suction head and surgical drape combination as claimed in claim 2 in  
which the adhesive-coated film is strengthened with a second plastics film which is  
15 thicker or less flexible than said adhesive coated film.
4. A suction head and surgical drape combination as claimed in claim 2 or 3  
wherein the adhesive coating on said flexible film is protected with a protective,  
releasable layer covering the area of the adhesive, said releasable layer comprising a  
separate strip protecting the adhesive coating in the vicinity of the suction head and said  
20 strip carrying a flap overlapping an adjacent portion of the releasable layer and  
constituting a handle to facilitate removal of said strip prior to use.
5. An assembly for use with a source of suction for stimulating healing of  
wounds which comprises a foam pad comprising an open-celled flexible polymer foam  
and a suction head and drape as claimed in claim 4.



6. A suction head for applying suction to a wound area substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings.

5 DATED this 10th day of January, 2002

KCI MEDICAL LIMITED

Attorney: RUSSELL J. DAVIES  
Fellow Institute of Patent Attorneys of Australia  
of BALDWIN SHELSTON WATERS

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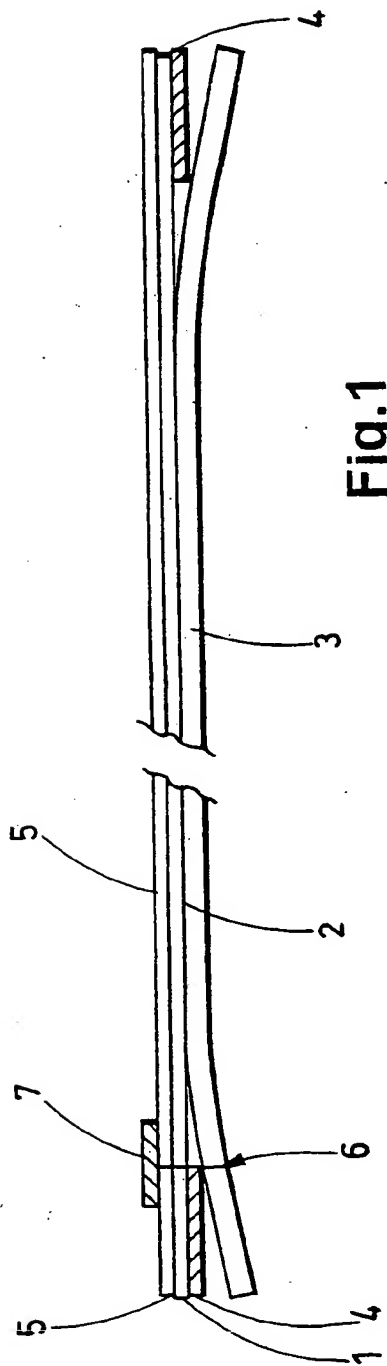


Fig. 1

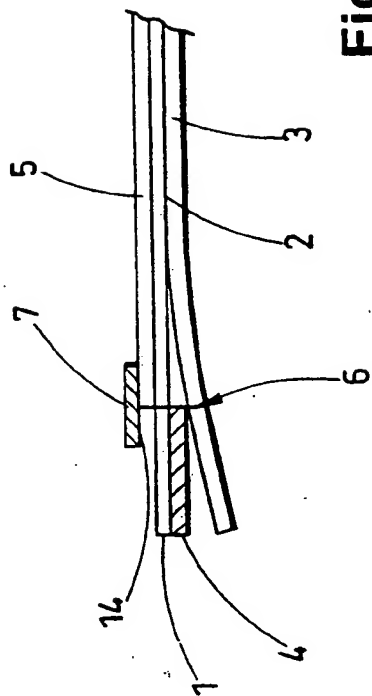


Fig. 2

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Fig. 3

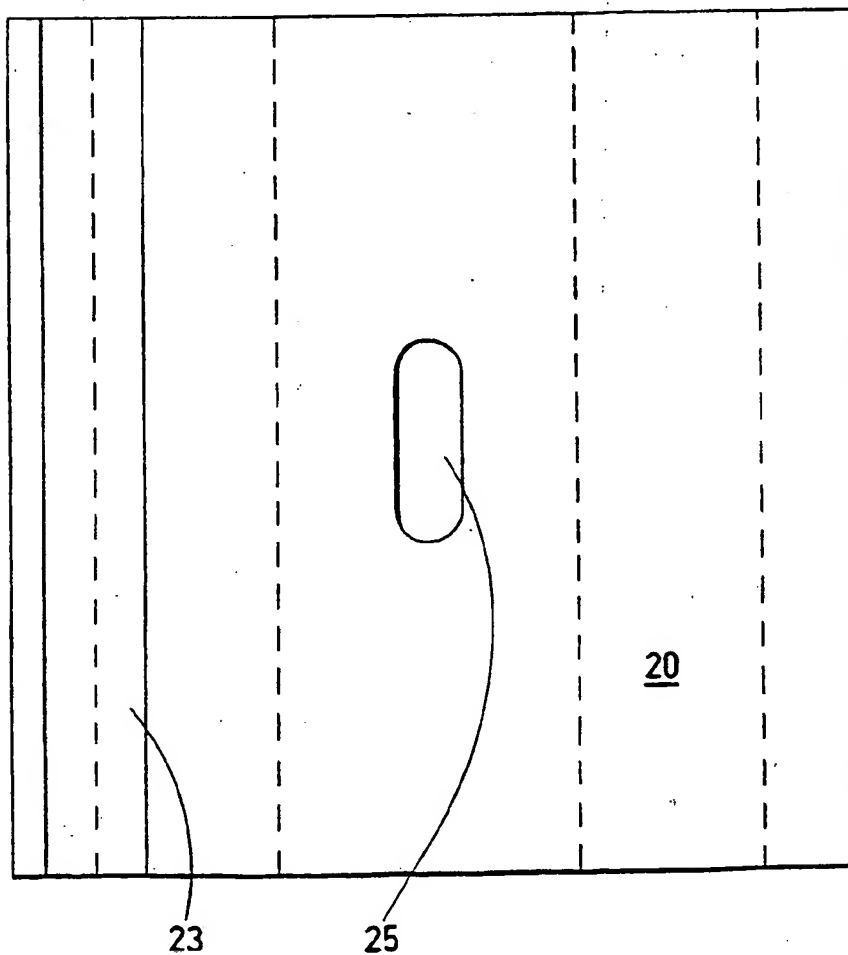


Fig. 4

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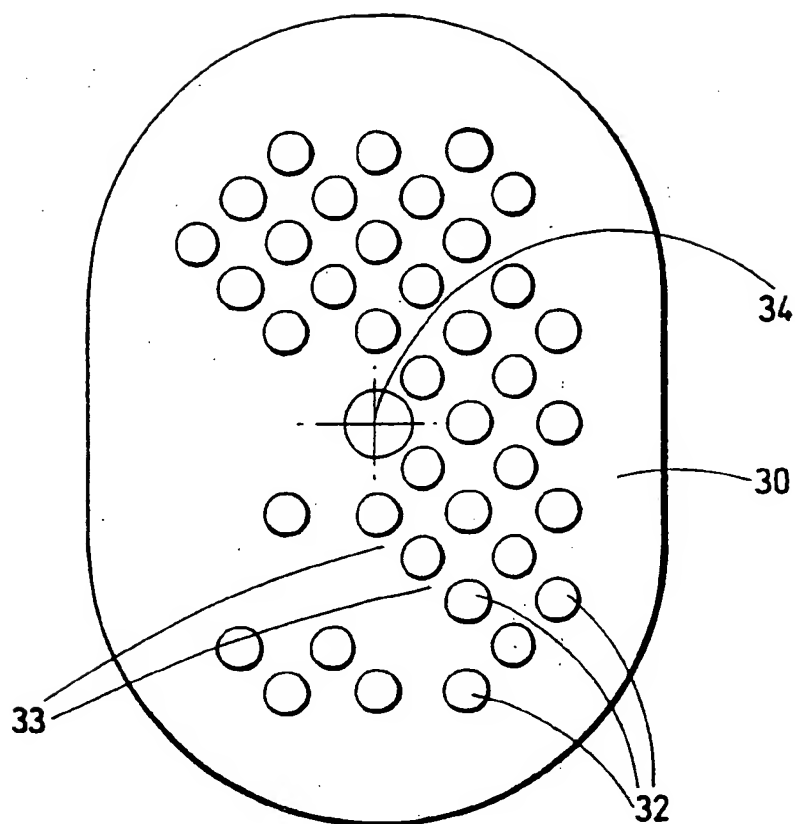


Fig. 5

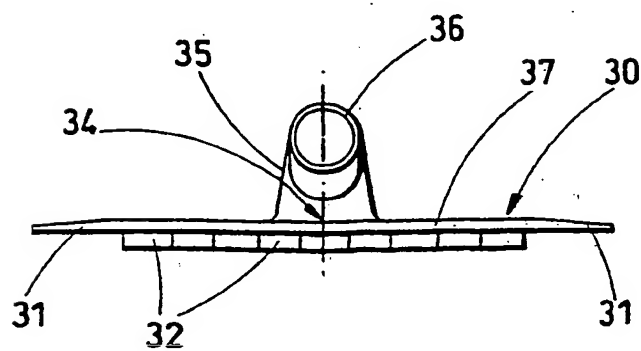
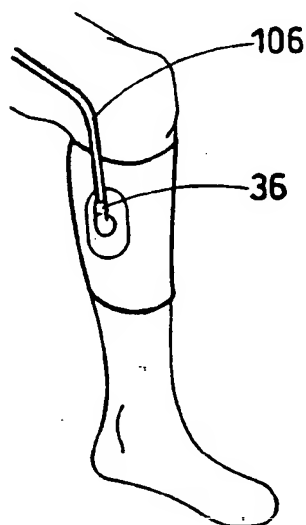
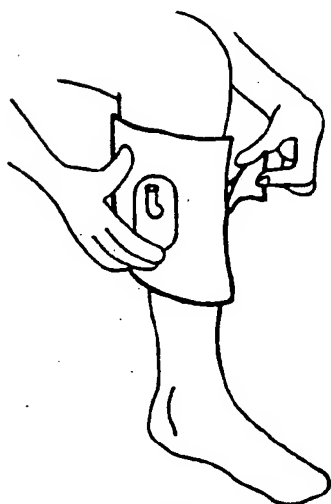
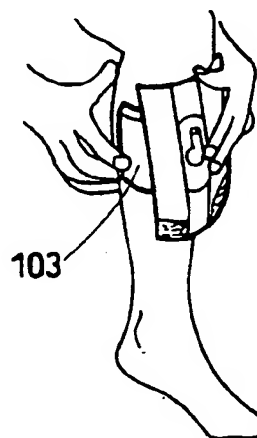
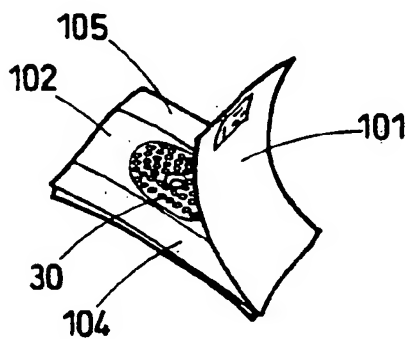
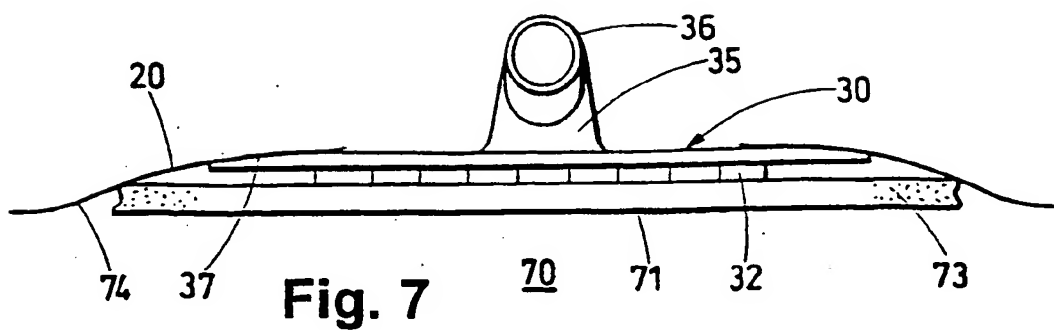


Fig. 6





Commonwealth  
of Australia

# Letters patent

Patents Act 1990

No.  
755496

## STANDARD PATENT

I, Fatima Beattie, Commissioner of Patents, grant a Standard Patent with the following particulars:

**Name and Address of Patentee:**

KCI Medical Limited, Two Rivers Station Lane Witney Oxfordshire OX8 6BH United Kingdom

**Names of Actual inventors:** Keith Patrick Heaton and Kenneth William Hunt

**Title of Invention:** Surgical drape and suction head for wound treatment

**Application Number:** 97360/01

**Term of Letters Patent:** Twenty years from 9 September 1998

**Divisional of:** 745271

Dated this 24 day of April 2003



F. BEATTIE  
COMMISSIONER OF PATENTS

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**(19) AUSTRALIAN PATENT OFFICE**

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**(10) Patent No. 755496**

**(54) Title**  
**Surgical drape and suction head for wound treatment**

**(51)<sup>7</sup> International Patent Classification(s)**  
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**(62) Divisional of:**  
**199889934**

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**(56) Related Art**  
**EP 117632**  
**WO 9718007**

# AUSTRALIA

PATENTS ACT 1990

## COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Actual Inventor/s: Keith Patrick Heaton and Kenneth William Hunt

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60 MARGARET STREET  
SYDNEY NSW 2000

CCN: 3710000352

Invention Title: 'SURGICAL DRAPE AND SUCTION HEAD FOR WOUND  
TREATMENT'

Details of Original Application No. 89934/98 dated 9 September 1998

The following statement is a full description of this invention, including the best method of performing it known to us:-

File: 27471AUP01

### Surgical Drape and Suction Head for Wound Treatment

This invention relates to surgical drapes and suction heads for wound treatment.

Surgical drapes are widely used in surgical operations for the purpose of reducing infection and facilitating the handling of skin around incisions. Normally, they are transparent or translucent. Typically, they consist of a flexible, plastics film which is adhesive-coated and which is applied to the area of the operation, prior to making the incision. Surgical drapes are also used for attaching treatment devices to patients after an operation, such as catheters or drainage tubes.

A further, recently developed use is for connecting a suction tube to a wound for the purpose of stimulating healing of the wound. Such use is described in our earlier PCT Applications Nos. WO 96/05873 and WO 97/18007.

Various proposals have been made in the past to design the surgical drape so that handling of the sticky, flexible, plastics film is facilitated. For example, US Patent No. 5,437,622, describes a surgical drape which is a laminate of three materials. The first material comprising a transparent, thin plastics film which is adhesive-coated and this is protected with a layer of release-coated paper. The other face of the adhesive-coated film is strengthened with a reinforcing layer of a less flexible, plastics film. Handling bars or strips are attached to the flexible, plastics film at its lateral edges to facilitate handling of the flexible, plastics film after stripping away the protective releasable layer.

Where it is desired to use a surgical drape primarily to attach a device such as a catheter to a wound area after an operation or for long term treatment, it is inconvenient for the surgeon or nurse to have to adapt a standard surgical drape for this purpose. It would be more convenient to have a surgical drape which was suitable without adaptation to accommodate the treatment device.

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

It is an object of the present invention to overcome or ameliorate at least one of the  
5 disadvantages of the prior art, or to provide a useful alternative.

Accordingly, the invention provides a surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer  
10 applied to the adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and  
15 which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.

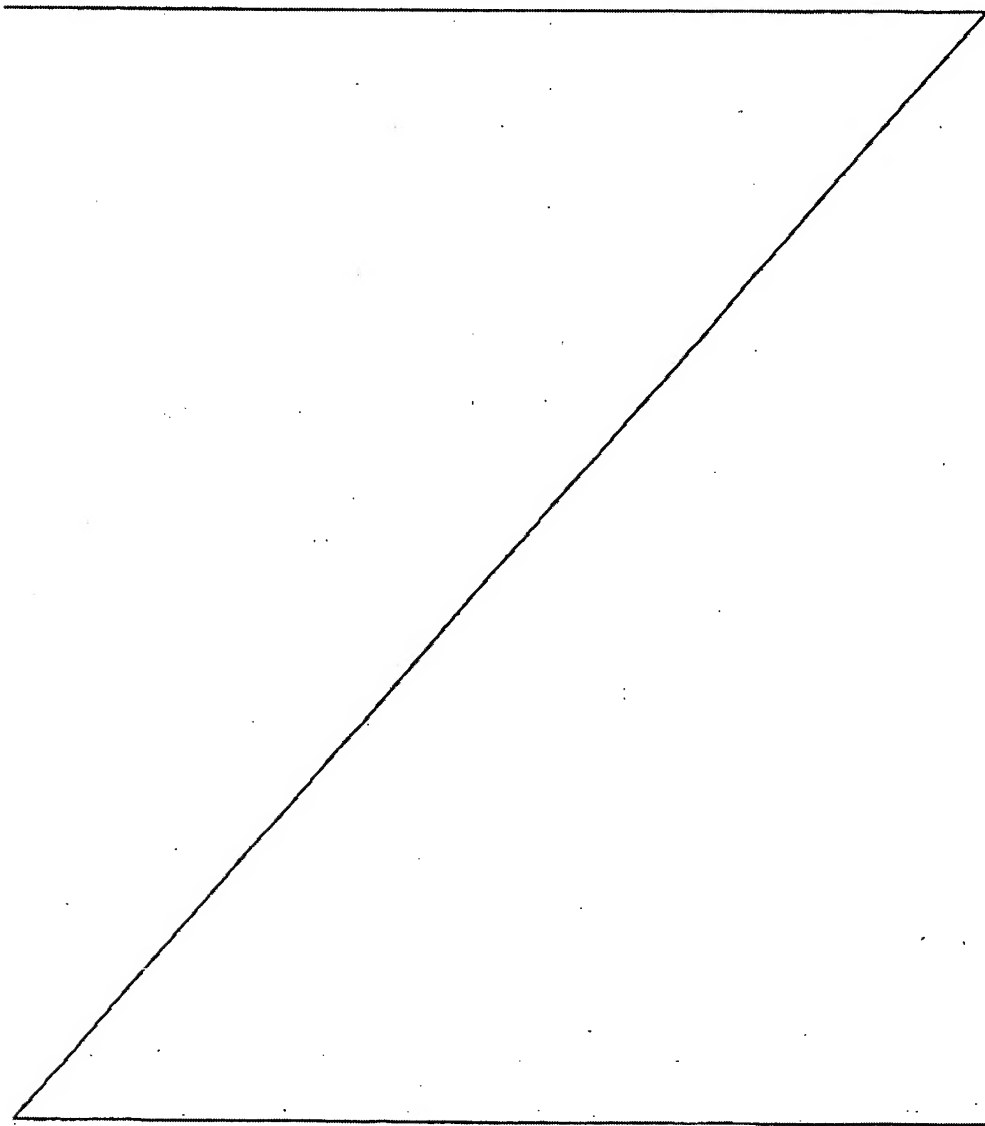
Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an  
20 inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

Preferably, non-adhesive-coated handling bars are positioned at opposite lateral edges of the drape.

In practice, surgical drapes may be manufactured by laminating an adhesive-  
25 coated flexible film, such as a polyurethane film, to a protective releasable layer, such as

a siliconised paper. A strengthening layer of thicker plastics material, e.g. a polyolefin such as polyethylene, may be applied to the non-adhesive coated face of the flexible film, so that a three-layer laminate is produced. These laminates are produced in substantial width and may be slit longitudinally to the desired width and then laterally to form drapes of the desired size.

After slitting to a desired width, handling bars are normally applied to the adhesive-coated layers at one or both lateral edges to facilitate separation of the film



from the protective, releasable layer. While an aperture could be cut at the desired position through the layers to accommodate a catheter or a device such as those described in our above-mentioned applications, it is difficult to handle the highly pliable and adhesive film after the releasable layer has been stripped off.

5        Although the strengthening layer does somewhat improve the handling characteristics, this is not a complete answer to the problem. However, the handling characteristics are substantially improved by providing a protective layer which is in at least two portions, one of which is in the form of a strip, e.g. one extending parallel to the lateral edges of the drape, and covering the peripheral area around the aperture  
10 through the drape. By providing a flap on this portion of the releasable layer, it can be stripped off initially so that the drape is first positioned around the device which is to pass through the aperture, and then the remaining part of the protective releasable layer is stripped off to adhere the drape to the patient's skin around the area to be treated.

      In a preferred form of the invention in which negative pressure therapy is applied  
15 to a wound area, the surgical drape described above is combined with a suction head having a connector piece which is adapted to be connected to a suction tube. Thus, in this embodiment, the suction head can be adhered to the patient's skin in the area of the wound after removing the strip of protective releasable layer, and then the remaining part of the drape affixed to the patient's skin. In this way, the suction head is held firmly  
20 in place and, at the same time, seals the suction head to the wound area and prevents leakage of air from atmosphere into the wound area.

      The invention also preferably includes a suction head having a design which facilitates the suction of fluid from a wound area.

      According to a further preferred feature of the invention, therefore, there is provided  
25 a suction head for applying suction to a wound area which comprises a generally planar

flange portion and a tubular connector piece on a first face, for connecting a suction tube to an aperture through the flange portion to the other face, said other face having projections defining flow channels facilitating flow of fluid towards said aperture.

Preferably, the suction head described above is combined with a surgical drape, the  
5 drape comprising a thin, flexible, adhesive-coated plastics film, and the tubular connector piece extends through an opening in the plastics film with the adhesive coating adhered to said first face of the flange portion.

Preferably, the suction head is used in conjunction with an open-celled foam pad so that one surface of the foam pad is placed in contact with a wound area and the  
10 suction head applied to the other surface of the foam pad. In the case of deep wounds the foam may be shaped and placed so that it is packed into the wound cavity as described in our above cited PCT applications. According to another technique, which is particularly applicable to superficial wounds, the foam pad may be a relatively thin pad which is placed over the wound. The suction head is placed in contact with the open  
15 face of the foam pad and the drape applied over the suction head to fix the assembly to the patient's skin.

Various types of open celled foams can be used as described in our above cited PCT applications. The foam may be a polyurethane foam but polyvinyl acetate (pva) foams are preferred, especially when used as a pad which is placed over the wound.  
20 These are to some extent hydrophilic, which seems to exhibit beneficial comfort properties when applied to the skin. Wound healing is stimulated by maintenance of moist conditions in the wound area, and this is facilitated by using a hydrophilic foam.

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

25 Referring to the accompanying drawings:

Figure 1 represents a conventional design of surgical drape;

Figure 2 represents a variation in the design of the handling bars at one end of the drape shown in Figure 1;

Figure 3 is a view similar to Figure 1 of a surgical drape in accordance with the invention;

Figure 4 is a plan view of the surgical drape shown in Figure 3;

Figure 5 is a plan view from beneath of a suction head in accordance with the invention; and

Figure 6 is a side elevation of the suction head shown in Figure 5;

Figure 7 is a view similar to Figure 6 but shows the suction head secured to a skin surface with the drape and with a foam pad located between the head and the skin surface.

Figure 8 is a perspective view of the drape with a central strip portion of the protective sheet in the course of being removed, and

Figures 9(a)-9(c) illustrate the steps of affixing the dressing assembly to a wound area on a patient's leg and attachment to a negative pressure assembly.

Referring to Figures 1 and 2 of the accompanying drawings, a conventional laminate for use as a surgical drape comprises a thin, flexible, transparent plastics film 1 which is adhesive-coated on one face 2, normally with a high-tack pressure-sensitive adhesive, and is protected with a releasable layer 3. The thin plastics film is conveniently of polyurethane because it transmits moisture. Layer 3 is normally considerably thicker than film 1 and is coated on the surface adjacent to the adhesive with a releasable material such as a silicone to facilitate stripping away from the adhesive-coated film.

In order to facilitate removal of the adhesive-coated film prior to use of the device, handling bars 4 are bonded at each end to the adhesive-coated film 1. Thus,

by holding one of the bars 4, the protective layer 3 can be stripped off and the adhesive face applied to the skin of the patient. To facilitate handling of the thin, flexible film 1, a strengthening plastics film 5 is frequently applied to the free face of the plastics film 1. This is generally also transparent or translucent. Film 5 is preferably not bonded with adhesive to film 1, but may remain in contact by reason of electrostatic forces or because of close contact between the two conforming surfaces of film 1 and film 5.

Usually, the surgeon or nurse will wish to strip off the protective layer 5 after the film 1 has been correctly placed on the patient's skin, and this can be facilitated by making partial cuts 6 through the films 1 and 5, so that as the handling bar 4 is drawn upwards from the patient's skin, the adhesive film 1 remains adhered to the patient, while the partial cuts 6 causes separation of the flexible film from the strengthening film 5. Strengthening bars 7 may be provided to hold the lateral edges of the strengthening film 5 and film 1 together with their main parts.

An alternative arrangement is shown in Figure 2, in which the strengthening film 5 is provided with a separate overlapping handling bar 14, to facilitate its removal from the flexible film 1.

Further details of the make-up and manufacture of surgical drapes are given in US Patent No. 5,437,622 and European Patent Application No. 0161865 and the prior art referred to therein, the disclosure of which is incorporated herein.

Referring to Figure 3 and 4, the surgical drape of this invention comprises a protective outer film 20, laminated to a thin, flexible film 21. The flexible film 21 includes an adhesive-coated layer which is protected with a release-coated sheet material 24. Lateral edges of the flexible film 21 are provided with handling bars 23. Thus far, the design is essentially the same as that shown in Figures 1 and 2.

The drape of the present invention differs from the drape shown in Figures 1 and 2 in that an aperture 25 is cut through the strengthening layer 20 and through the flexible layer 21. The other difference compared with the prior art drapes is that the protective releasable layer is formed in at least two sections.

5 In the embodiments shown in Figures 3 and 4, the central portion of the releasable layer comprises a strip 26, having flaps 27 which overlap the remaining outboard portions of the releasable layer. The purpose of this is to enable the central strip 26 to be removed first, without disturbing the remaining portions of the releasable layer. The drape can then be fitted around the wound area and, if desired, a suction device or other treatment device passed through the aperture 25 and secured to the  
10 patient's skin with the peripheral areas of exposed adhesive-coated film.

An example of a device for applying suction to the wound area is illustrated in Figures 5, 6 and 7.

Referring to these Figures, the suction head comprises a flange portion 30 having a tapered edge 31, and a profile which may be of any desired shape but is generally rounded at its edges. On the face of the flange 30 intended for contact with  
15 the patient's skin or a foam pad are formed a series of projections 32 which are distributed over the surface of the flange apart from the peripheral edge portion 31. The purpose of these projections is to provide fluid channels 33 facilitating the flow of fluids from any point of the flange to a central point 34, from which it is intended to apply suction. The suction head includes a connector 35, located above the aperture  
20 34, having a tubular end 36 adapted for receiving and connecting a catheter. The tubular end may have an outwardly tapered portion to facilitate feeding a catheter into the connector. The upper surface 37 of the suction head has a substantially smooth surface.

In use, the connector portion 35 is sized so that it extends through the aperture 25 in the surgical drape shown in Figures 3 and 4, with the adhesive surface around the aperture bonded to the smooth surface 37 of the flange 30. The suction head may be packaged in this condition with the surgical drape so that in use, the strip 26 is removed by pulling on the handles 27 thus exposing the adhesive surface in the vicinity of and surrounding the suction head. The suction head can then be fixed in the desired position on the patient's wound and then the remaining portion of the protective film removed to fix the drape to the patient. The flange 30 of the suction head may be somewhat oval as shown in Figure 5, and have dimensions as indicated in this Figure, i.e. a longer dimension of about 95mm and a short dimension of about 70mm. Alternatively, the flange may be circular and be smaller in plan view. For example, the diameter of a circular suction head may be from about 30 to 50mm in diameter, e.g. about 40mm. It has been found that the suction head flange should not overlap the area of the wound. Thus, in the case of smaller wounds a smaller suction head is indicated.

Figure 7 shows the suction head attached to a wound area 71 of a patient 70. The suction head is pressed into firm contact with a flexible, open-celled foam 73, which is itself pressed into contact with the wound area 71. The suction head and foam pad are pressed into contact with the wound area by a surgical drape 20 having an adhesive surface 74. The adhesive surface is bonded to the patient's skin outside the periphery of the foam pad and suction head. It is also bonded to upper surface 37 of the suction head. An aperture is formed in the drape to permit the connector portion 35 to extend upwardly through the drape. In order to avert the danger of incorrect catheter tubes being fitted to the connector 35, the latter may have a customised cross-section or internal projection such as a rib or key which co-operates with a corresponding slot or key way in the catheter. Alternatively, the catheter may

be moulded with a projection or longitudinal rib which co-operates with a corresponding slot or key way in the aperture of the connector 35.

The foam pad may be packaged in a plastic pouch, sterilised by gamma irradiation and supplied in the same box or in other packing units as the suction head and drape.

5        Figures 8 and 9(a)-(b) illustrate the way in which the drape/suction head combination is fitted to a wound on a patient's skin. In Figure 8, a backing sheet 101 having a release coated surface is removed in the first step from the adhesive face 102 of the drape to expose the face of the connector 30. A pad 103 of foam is positioned over the wound area and the drape placed over the foam pad, the drape being adhered to the  
10        skin above and below the pad (Figure 9a). The lateral protective strips 104 and 105 are removed in turn from the drape and the assembly adhered to the skin (Figures 9(b) and 9(c)). Finally, the spout 36 is connected to a tube 106 which is then connected to a source of suction, e.g. a pump as described in our above PCT application, in order to apply negative pressure to the wound. The suction head and drape assembly is shown in  
15        Figure 8, with the smooth surface 37 adhered to the drape, is conveniently packaged in an easily openable plastic bag or pouch, and sterilised for immediate use.

Although the invention has been described with reference to specific examples it will be appreciated to those skilled in the art that the invention may be embodied in many other forms.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A surgical drape which comprises a thin, flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the
- 5 strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, the drape having an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the
- 10 protective layer, and wherein the protective layer comprises a separate strip extending parallel to the first edge of the drape, and which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.
- 15 2. A surgical drape substantially as herein described with reference to any one of the embodiments of the invention illustrated in the accompanying drawings.

DATED this 21st Day of December, 2001

KCI MEDICAL LIMITED

Attorney: STUART M. SMITH  
Fellow Institute of Patent Attorneys of Australia  
of BALDWIN SHELSTON WATERS

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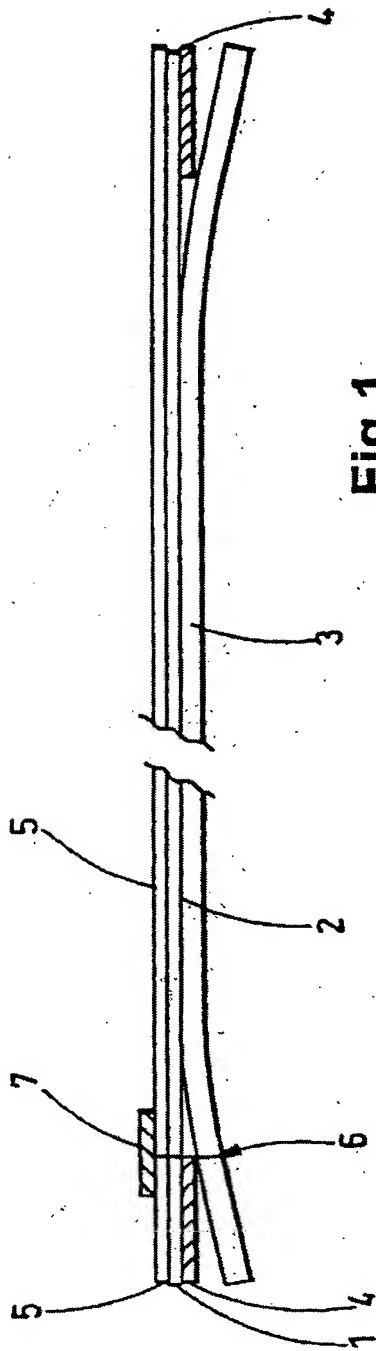


Fig. 1

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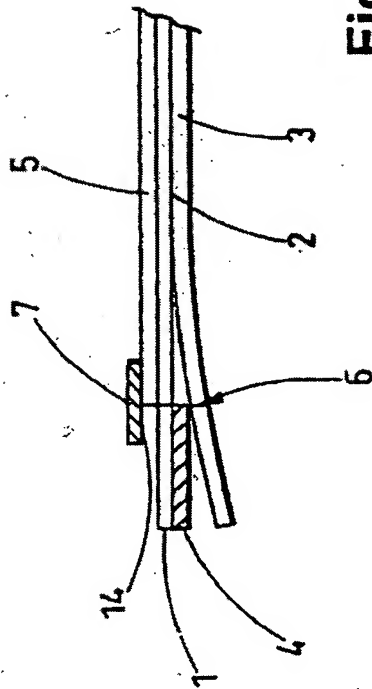


Fig. 2

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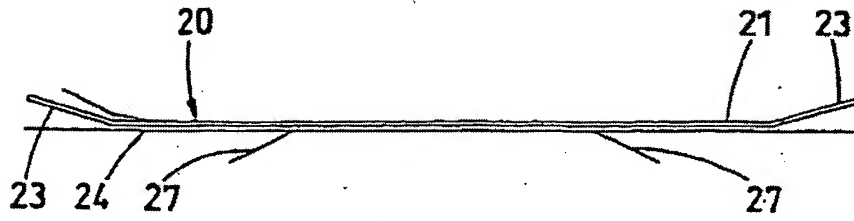


Fig. 3

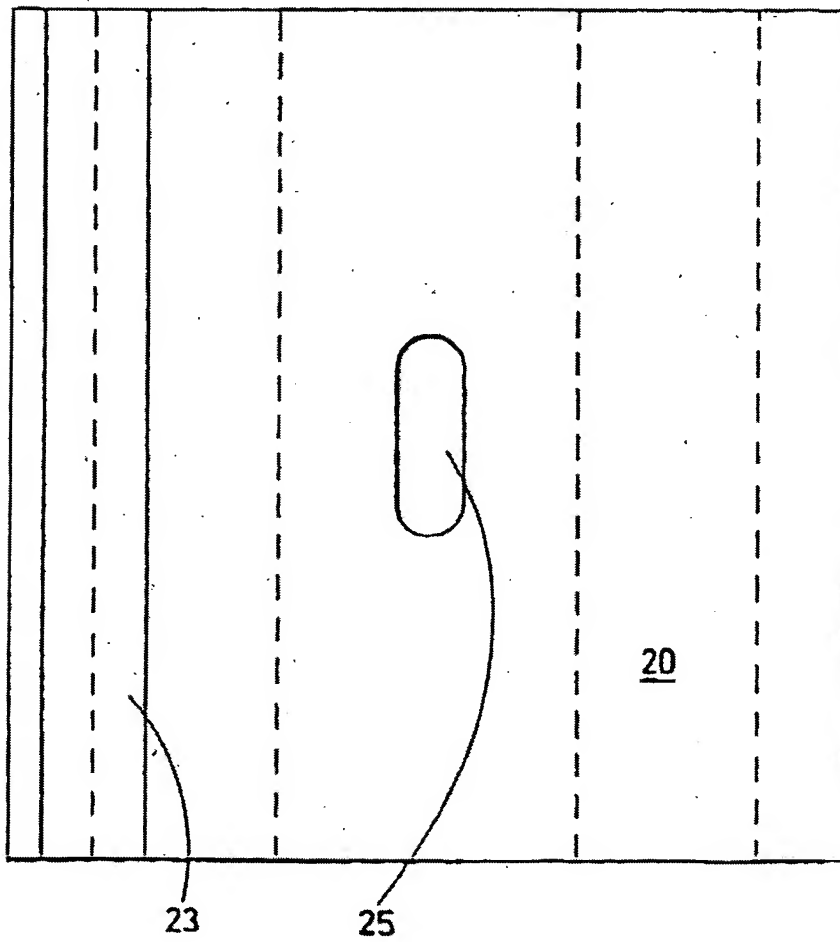


Fig. 4

3/4

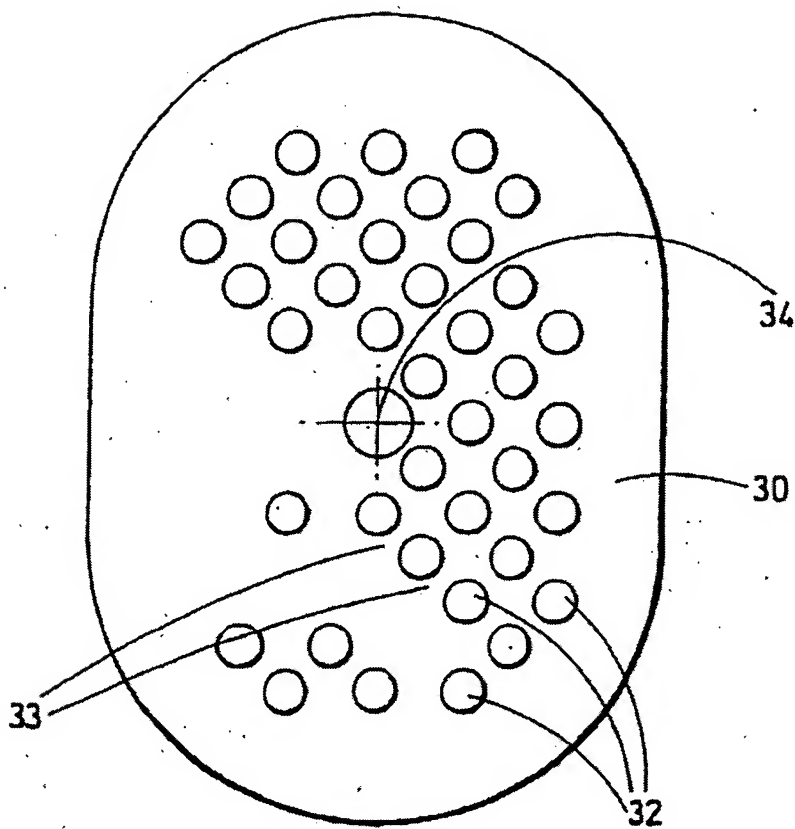


Fig. 5

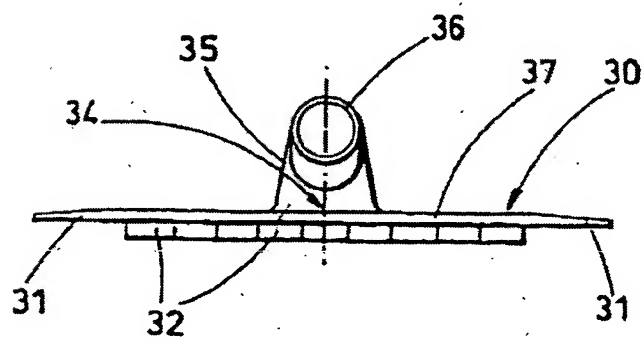


Fig. 6

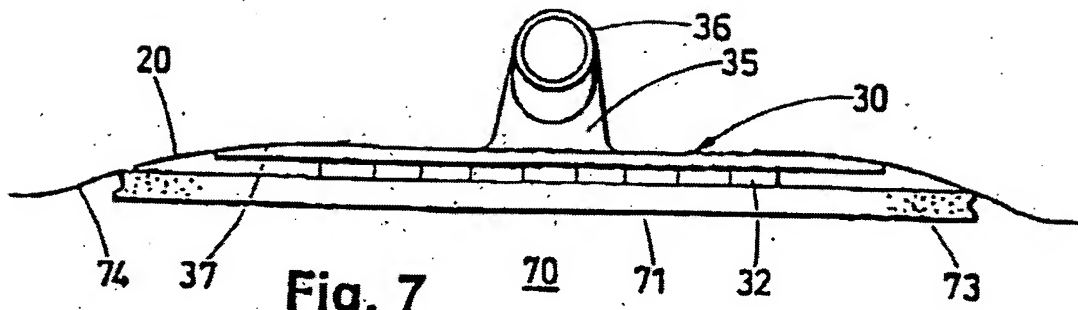


Fig. 7

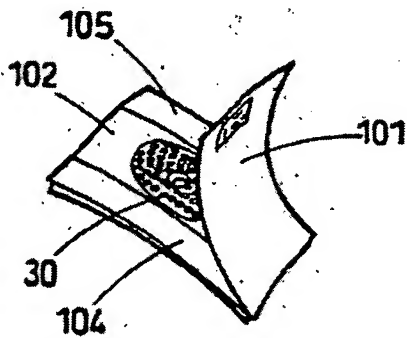


Fig. 8

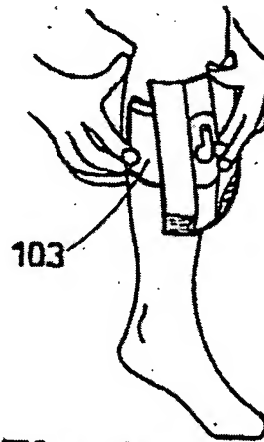


Fig. 9a

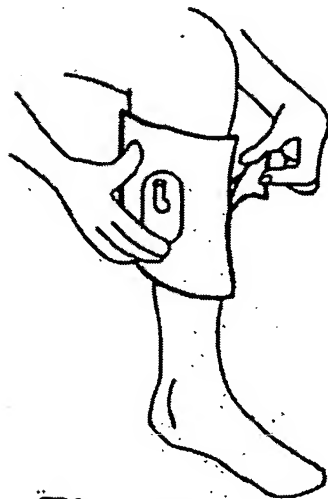


Fig. 9b

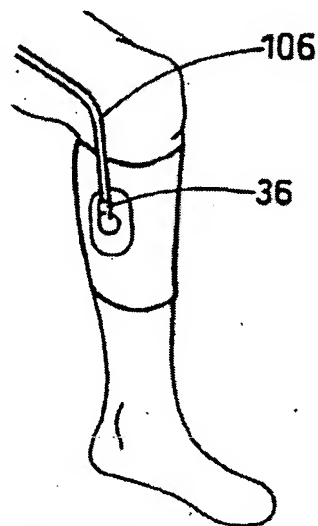


Fig. 9c



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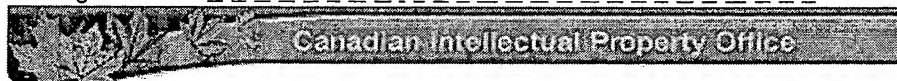
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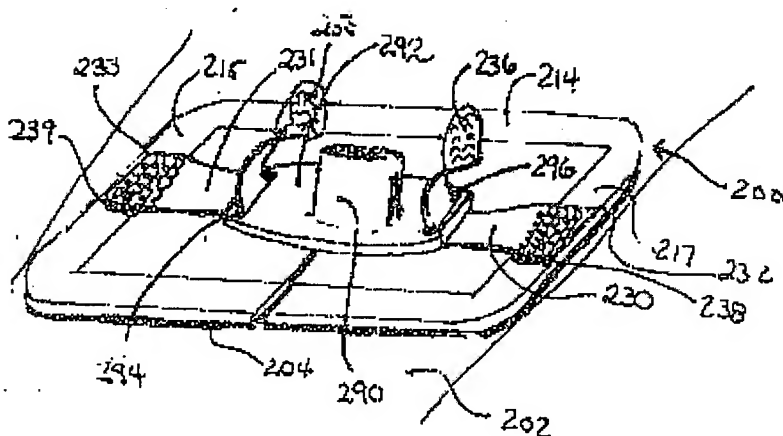
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(54) TRANSPARENT TRACHEOSTOMY TUBE DRESSING

(54) PANSEMENT TRANSPARENT POUR TRACHEOTOMIE

Representative Drawing:



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### ABSTRACT:

#### ABSTRACT

A transparent dressing for substantially sealing a wound consisting of a semi-rigid frame for defining an opening and a resilient transparent membrane member substantially covering the opening in order to form a transparent window. The transparent material allows air and vapors to permeate the material in a first direction and prevent contaminants and fluids from entering the wound area in an opposite direction. Several embodiments of the invention are shown for firmly holding tracheostomy tubes to the dressing.

CLAIMS: [Show all claims](#)

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## TRANSPARENT TRACHEOSTOMY TUBE DRESSING

BACKGROUND OF THE INVENTION

The present invention relates in general to a tracheostomy tube dressing for covering the wound about a patient's neck such that the wound area can be covered while it is also allowed to heal.

Although opaque dressings have long been in use, their designs suffer from several drawbacks. First, the patient or person treating the patient has no idea how well the wound is healing until the dressing is entirely removed. Second, removal of the dressing increases the danger that the scab or skin covering the wound will be removed along with the dressing. Another drawback is that many dressings fail to adequately aerate the wound. In such instances, the healing of the wound is much slower. Another drawback of many conventional dressings is that part of the wound area is contacted by an adhesive portion of the dressing. Thus, when the dressing is removed, the tacky surface of the dressing will possibly harm the partially healed area.

These drawbacks are compounded in tracheostomy tube dressings where the dressing must serve the dual function of protecting the wound and holding the tracheostomy tube in place. Such a dressing must avoid the above drawbacks common to all dressings and still present a sufficiently rigid clamp for the tracheostomy tube.

To date, these transparent dressings and tracheostomy dressings that have been devised fail to avoid these drawbacks.

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For example, the 3-M Corporation markets a transparent dressing under the trademarked name "TECADERM" and the Johnson & Johnson Company sells a transparent dressing under the name "BIOCLUSIVX". Both dressings consist of a transparent air and vapor permeable film that have the surface of one side entirely coated with an adhesive. The dressings are supplied with releasable paper frames adhered to the non-adhesive side of each sheet. A paper frame is used in each dressing to maintain the integrity of the dressing's shape before it is applied to the patient's skin. Once applied, the frame is removed.

Although the "TECADERM" and "BIOCLUSIVE" dressings are relatively simple in their construction, their adhesive surfaces may harm healing tissue when the dressings are removed. Another problem is that water or contaminants may seep into the wound site from the sides of the dressing due to the lack of a sealing frame.

The "TECADERM" product also includes a design for use as a tracheostomy dressing. In this application, a slit is cut to extend from an edge of the dressing to the center. A center hole having the same diameter as a tracheostomy tube is then cut so that the slit contacts one side of the hole. The combination of the slit and center hole allow the bandage to be spread apart along the slit in order that a tracheostomy tube and cuff can easily slide into the center hole. When the slit is closed, the center hole surrounds the tube below the cuff and collar substantially enclosing the tube. However, the "TECADERM" tracheostomy dressing does not contain a structure for securing the tracheostomy tube to the patient's neck. Instead, the tube is independently secured to a patient's neck by means of cloth ties which completely encircle the patient's neck. Thus, the cloth ties do not adequately hold the tube to the bandage. Movement of the ties or of the dressing will cause stress on the tube. The cloth ties also create a substantial risk of infection to

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patients having undergone recent surgery to the head and/or neck. Moreover, if the ties are made too tight, they can potentially choke the patient. The cloth ties are also susceptible to bacteria, creating a greater risk of infection around the puncture area for the tube. The cloth ties also create a substantial risk of infection to patients having undergone recent surgery to the head or neck. Finally, the cloth ties are inconvenient, requiring the treating nurse or physician to physically untie or retie a knot each time they wish to remove or adjust the tube.

Another transparent dressing is sold under the registered trademark "VENI-GARD" by the Conmed Corporation. "VENI-GARD" is a disposable dressing for holding an IV needle or catheter in a patient's vein. The "VENI-GARD" provides a sterile barrier over the puncture site and incorporates a transparent semi-permeable membrane material as the covering over the site. The purpose of the transparent membrane is to allow unobstructed visualization of the puncture locus while at the same time enabling the evaporation of any moisture that collects around the puncture site. However, the construction of the VENI-GARD dressing is complex. Further, the membrane is coated with an adhesive that renders the VENI-GARD unsuitable for use in covering a wound because the adhesive surface may harm the healing tissue when the dressing is removed.

Another example of a transparent dressing is shown in the Gordon patent, U.S. Patent No. 4,341,208. The Gordon dressing has a transparent window and a flexible frame for adhering the window to the patient's skin. Thus, unlike "VENI-GARD," the Gordon dressing does not contact the adhesive layer to the wound. However, the material used with the window does not allow for the passage of air or moisture from the patient's skin to the exterior surface of the dressing. Moreover, the construction of the Gordon dressing requires a multiple layered

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window which employs an applicator layer adjacent to the transparent layer. The applicator spaces the window from the skin by the thickness of the frame which is not as sterile as an adjacent film because the spaced film traps air or other substances adjacent to the skin.

Another transparent dressing is illustrated by the Klein patent, U.S. Patent No. 2,273,873. The Klein dressing involves a transparent adhesive sheet adapted to be used as a dressing for a wound. The wound is not sealed from outside contaminants since air passages are provided along portions of the frame of the dressing. In addition, the transparent material used in the Klein dressing is neither air nor vapor permeable, and the sheet does not contact the skin.

The Linsky et al. patent, U.S. Patent No. 4,181,127, illustrates a non-adherent wound dressing employing an absorbent pad border that removes moisture from the area around the wound. A transparent film covers the wound and has its edges overlapped by an adhesive frame. However, the film is placed on top of the frame rather than below it, the materials of the frame are primarily webbing, and the film is an imperforate material that does not offer the advantages of a transparent air/vapor permeable barrier.

The Merriam et al. patent, U.S. Patent No. 2,949,443, illustrates a water vapor permeable dressing applied directly to a surgical wound. The material of the dressing is primarily transparent and water and vapor permeable. However, the material is either applied to the skin through the use of an adhesive layer formed along the outer edge of the dressing, or through the application of an alcohol solvent applied to the skin directly. Such a construction does not adhere strongly to the patient's skin and may easily come loose from the wound area.

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The Faasse, Jr. patent, U.S. Patent No. 4,744,955, discloses a hinged releasable wound dressing in which a thin flexible polymeric film having an adhesive layer coated on one side of the dressing is applied directly to the site of the wound. The Faasse, Jr. dressing has the drawback of directly contacting the wound with adhesive which could cause the healing layer of skin to be pulled up when the dressing is removed.

Finally, the Dallas dressing illustrated in U.S. Patent No. 4,485,809 provides for a transparent moisture vapor permeable film dressing. As in Faasse, Jr., the Dallas film also employs an adhesive in order to directly contact the dressing to the patient's skin. Therefore, the construction of the Dallas dressing can cause tearing of the partially healed wound when the dressing is removed from the patient's skin.

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SUMMARY AND OBJECTS OF THE INVENTION

The present invention alleviates to a great extent the disadvantages presented by the prior art devices by providing for a transparent tracheostomy dressing of simple construction that completely seals a wound with a transparent gas/vapor permeable membrane, while avoiding contact between the dressing's adhesive surface and the wound. Moreover, the dressing secures the tracheostomy tube to the frame of the dressing such that the tube is firmly supported. The material of the transparent member is gas/vapor permeable only in the direction away from the wound such that outside contaminants cannot enter inside the dressing. The frame that adheres the transparent membrane to the wound is sufficiently rigid to adequately secure the tracheostomy tube yet sufficiently flexible so that the dressing can be comfortably worn while not folding over itself when applied to the skin.

The transparent dressing is substantially rectangular. The frame portion consists of a rectangular piece having a centrally defined opening. A similarly shaped but smaller rectangular transparent membrane is attached to the bottom of the frame such that a tacky adhesive border surrounds the transparent membrane. Two ties are adhered to opposing sides of the frame. The ties are oriented to loop around a tracheostomy tube located in the center of the rectangular opening. Moreover, a slit runs from one edge of the frame to the center of the transparent membrane. A center hole is formed out the center surrounded by a frame formed about the circumference of the center hole.

In another aspect of the invention, the dressing is substantially circular.

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In still yet another embodiment of the invention, the dressing has a frame with two fingers at opposing ends of the frame. A transparent window is formed in the center of the frame.

It is an object of the invention to provide for a transparent dressing yielding to the foregoing advantages that effectively holds a tube against a patient's body.

It is still an additional object of the invention to provide for a transparent dressing where the dressing does not have to be removed in order for the patient to observe the site of the wound.

It is still a further object of the invention to provide for a dressing of simple construction having a frame consisting of a single piece of material.

It is still a further object of the invention to provide for a dressing yielding to the foregoing advantages and that can clamp to a variety of sizes of tubes and yield to any skin surfaces of the body.

It is still an object of the invention to provide for a dressing that securely clamps a tracheostomy tube to the neck of a patient without requiring the use of cloth ties.

These and other objects of the invention are accomplished by the present invention as described by the drawings and detailed description herein.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top view of the first embodiment of a transparent dressing according to the present invention;

FIG. 2 is a cutaway view taken along section line II-II of FIG. 1;

FIG. 3 is a bottom view of transparent dressing 10 of FIG. 1;

FIG. 4 is a perspective view of a second embodiment of a transparent dressing according to the present invention;

FIGS. 5a-5b are top views of a third embodiment and fourth embodiment of a transparent dressing according to the present invention;

FIGS. 6a-6b are perspective views of the fifth embodiment of FIG. 5a in use;

FIG. 7 is a perspective view of a sixth embodiment of the transparent dressing of the present invention;

FIG. 8 is a top view of a seventh embodiment of the transparent dressing of the present invention; and

FIGS. 9a-9b are respectively perspective views of the first embodiment in use and the seventh embodiment in use.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As referred to herein, the inner surfaces of various component parts of the preferred embodiments of the present invention are those surfaces oriented towards the object to which the dressing is adhered. Similarly, the outer surfaces of the various component parts of the preferred embodiments are those surfaces oriented away from such an object. Such an object may be any kind that is used for transparent dressings but will most likely be a patient's skin, their clothing, hair, or the like.

Referring now to the figures, wherein like parts are represented by like reference numerals, FIGS. 1-3 illustrate a first embodiment of the present invention designated by reference numeral 10. In the first embodiment, a transparent dressing 10 is shown. This embodiment is particularly suited for use in covering the wound of a medical patient. The transparent dressing 10 is designed such that it includes a centrally located opening 12. A frame surrounds the opening 12 creating a window at the center of the dressing 10.

The frame is preferably formed from a stretchable adhesive electrode foam material. Suitable materials for the frame include the adhesive foam marketed under the federal trademark "MACROLYTE" by the Conmed Company or marketed under the trademarked name, "MICROFOAM" by the 3-M Corporation. The advantages of such materials is that they are sufficiently flexible to be comfortably worn by the patient and sufficiently rigid to retain the shape of the dressing when it is not adhered to the patient's skin. Thus, the frame insures that the dressing will not fold upon itself during application or not retain its shape when packaged. Moreover, the foam material is substantially water-resistant, thus providing a barrier to contamination by bacteria or liquids.

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While the shape of frame 14 is shown as being rectangular in FIGS. 1 through 3, it can be formed into any desired configuration. It is to be noted that by incorporating different shapes and sizes, the dressing can more effectively accommodate different parts of the body. Thus, different shapes would necessarily be contemplated by the present invention to cover elbows, knees, fingers, bony prominences or different objects such as tubes or the like. For example, it is contemplated that the frame can be substantially oval, triangular or formed into a fanciful design such as a star, fish or heart. Other shapes of the present invention are illustrated in the remaining figures.

Returning now to FIG. 1, the opening 12 is enclosed along the bottom side by a transparent membrane 18. The membrane is adhered to frame 14 in such a manner that it cannot easily separate during use.

The material of the membrane 18 is preferably a hypo-allergenic non-adhesive flexible plastic that allows vapor and gases to escape through the material in one direction but blocks contaminants and moisture from coming into the material in a second direction. It is preferred that the material for membrane 18 is either "TEGADERM" marketed by the 3-M Corporation or "BIOCLUSIVE" marketed by the Johnson & Johnson Company. However, any other material having similar characteristics as described above can be employed.

The frame 14 is coated on its bottom surface with a medical grade adhesive, preferably a hypo-allergenic synthetic acrylic pressure sensitive adhesive. The adhesive is used to secure the membrane 18 to the frame 14 as well as to secure the frame 14 to the patient's skin. The acrylic adhesive is of sufficient tackiness to seal the wound from liquids or air seepage that may occur between the base of frame 14 and the

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patient's skin. The adhesive thus serves in combination with the frame to create a water tight barrier between the interior of the dressing and the exterior environment. However, the adhesive is sufficiently weak that the dressing 10 can be removed with a minimum of resistance.

FIG. 2 shows a cut-away view of a cross-section of dressing 10 taken along reference lines VI-II of FIG. 1. The membrane 18 is substantially smaller in width than the width of frame 14. When frame 14 is adhered to the membrane 18 by means of adhesive layer 15, those portions of frame 14 that extend beyond the membrane serve as an adhesive border that is used to adhere the dressing 10 to the patient's skin. Although adhesive layer 15 is shown covering the entire bottom surface of frame 14, different types of adhesives can be used on different portions of frame 14. For example, a stronger adhesive can be employed to adhere the membrane 18 to the frame portion 14 while a weaker adhesive can be used along the adhesive border.

In a preferred embodiment, a liner 16 extends substantially across the adhesive border of frame 14 and the entire bottom surface of membrane 18. As shown, the liner 16 adheres against the membrane as a result of the tacky adhesive surface 15. By employing liner 16, the membrane 18 is protected and the adhesive surface 15 remains unexposed. In use, the liner 16 is peeled off of the frame 14 exposing the tacky adhesive surface for contact with a patient's skin. The materials of the liner can consist of any conventionally used paper or plastic liner.

FIG. 3 is a bottom view of the first embodiment illustrated in FIG. 1. More particularly, FIG. 3 shows the relationship between the membrane 18 and the frame 14. The perimeter 17 of the frame 14 is of such dimension that it is substantially wider and longer than the perimeter 19 of the membrane 18. The difference in perimeters defines a border area 13 formed around

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the membrane 18. As the adhesive material 15 covers the surface area of border 13, the border provides a complete adhesive frame around the non-adhesive bottom surface of the membrane 18. The wound area, which is primarily covered by the membrane 18, will thereby not contact adhesive surface 15.

Referring now to FIG. 4, a second embodiment 100 consisting of a circular dressing, is shown. The dressing according to the second preferred embodiment of the invention is generally similar in construction to the first embodiment described in conjunction with FIGS. 1-4. One major difference between the first and the second embodiments, however, is flap 120 for covering the transparent opening 121.

The dressing 100 includes a frame 114 composed of a medical grade foam that is similar to that described for use with the first preferred embodiment. The base 114 is coated with a medical grade adhesive (not shown) along its bottom surface in order to adhere a transparent membrane to the frame and the frame to the patient's skin. The adhesive, in turn, can secure a circularly shaped membrane material 118 such that it surrounds and covers the opening 121. The circumference 119 of the membrane 118 is less than the circumference of frame 114. Thus, a border referenced by radial arrow 113 is defined by the differences in size of these two elements. As previously discussed, the tacky adhesive surface (not shown) on the border of frame 14 is employed to adhere the circular dressing 100 to the skin.

The dressing further includes a flap 120 which is formed integrally with the frame 114. As shown, the flap is configured to substantially fit within opening 121 to cover the surface of transparent membrane 118. In order to open the flap, it is folded back towards the frame along fold line 122.

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the membrane 18. As the adhesive material 15 covers the surface area of border 13, the border provides a complete adhesive frame around the non-adhesive bottom surface of the membrane 18. The wound area, which is primarily covered by the membrane 18, will thereby not contact adhesive surface 15.

Referring now to FIG. 4, a second embodiment 100 consisting of a circular dressing, is shown. The dressing according to the second preferred embodiment of the invention is generally similar in construction to the first embodiment described in conjunction with FIGS. 1-4. One major difference between the first and the second embodiments, however, is flap 120 for covering the transparent opening 121.

The dressing 100 includes a frame 114 composed of a medical grade foam that is similar to that described for use with the first preferred embodiment. The base 114 is coated with a medical grade adhesive (not shown) along its bottom surface in order to adhere a transparent membrane to the frame and the frame to the patient's skin. The adhesive, in turn, can secure a circularly shaped membrane material 118 such that it surrounds and covers the opening 121. The circumference 119 of the membrane 118 is less than the circumference of frame 114. Thus, a border referenced by radial arrow 113 is defined by the differences in size of these two elements. As previously discussed, the tacky adhesive surface (not shown) on the border of frame 14 is employed to adhere the circular dressing 100 to the skin.

The dressing further includes a flap 120 which is formed integrally with the frame 114. As shown, the flap is configured to substantially fit within opening 121 to cover the surface of transparent membrane 118. In order to open the flap, it is folded back towards the frame along fold line 122.

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The slit enables the tracheostomy tube dressing 200 to sufficiently accommodate insertion of the tube into hole 225 and inside the collar 229. In addition to tracheostomy tubes, the dressing of FIG. 5a is adaptable for use as a stoma or fistula dressing.

A pair of tracheostomy tube ties 230, 231 are mounted on the sides 215, 217 of the frame 214 in a manner that they are generally oriented perpendicular to the longitudinal axis of the slit 227. Each tie is made of a flexible material that is adapted to substantially retain its shape under tension. Each tie respectively includes a first end 232, 233 having an inner surface that is coated with an adhesive layer (not shown). An outer surface of each first end consists of a loop fabric pad 234, 235, which is attached to the flexible material in any conventional manner. Each tie 230, 231 further includes a respective second end 236, 237, having a hook material also adhered to the tie 230, 231. The size and orientation of the tie material is designed to allow the tie to loop around a tracheal tube collar (see FIGS. 6a, 6b) in order that each second end 236, 237 of each tie respectively loops around the collar and mates with each respective first end 234, 235. The provision of ties 230, 231 enables a tracheostomy tube to be firmly held in place without placing any stress on a patient's neck or exposing the trachea wound to potential contaminants.

FIG. 5b illustrates a fourth embodiment of the present invention. As shown, an oval tracheostomy tube holder 250 includes a foam frame 264 formed of a similar material to that described above. The frame defines an opening 231 which is substantially covered by a vapor and gas permeable transparent membrane 268. An upper collar 279 made of a tacky foam material, in turn, surrounds the tube hole 275 centrally located in membrane 268. Moreover, a slit 277 is formed extending radially

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from tube hole 275 to the edge of frame 264. A pair of tracheostomy tube ties 280 and 281 are mounted on frame 264, as described above, such that ends 282, 283 are adapted to loop around a tube and respectively mate with ends 284, 285.

FIGS. 6a and 6b illustrate the fifth embodiment 200 in use. The tracheostomy tube holder 200 is adhered to a user's skin 202 by means of an adhesive layer 204 located on the inner surface of frame 214. A tracheostomy tube 290 is secured at its cuff (not shown) by a collar 292. The collar 292 includes slots 294 and 296 located at respective ends of the collar adjacent frame sides 215 and 217. The tracheostomy tube ties 230, 231 are adhered to sides 215 and 217 by an adhesive layer 238 and 239 located underneath each first end 234, 235 of each of the ties 230, 231. The ties 230, 231 are then looped through slots 294 and 296 in order that their respective second ends 236, 237 can fold back over the collar 292 and mate with respective first ends 232, 233.

A slit 217 opens the tube holder 200 to accommodate the curve of the patient's neck. The tube is held firmly to the dressing 200 by means of the adhesive collar 229 such that the skin around the tracheostomy tube is both visible and substantially covered by the membrane 218.

FIG. 6b shows the clamp 200 mounted on a patient's skin 202. The tube collar 292 is securely tied onto the frame 214 by means of ties 230, 231 in the manner described above.

FIG. 7 illustrates a sixth embodiment 300 of the transparent dressing suitable for special application over raised portions of a patient's body. The frame 314 is formed of a substantially similar stretchable foam material to that described above. However, the frame includes a pair of finger portions 330 located at opposed ends such that the overall "H" shaped

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frame is formed. The arrangement of membrane 318, opening 312 and adhesive border 320 are identical to that described in the first through fourth embodiments of the present invention.

FIG. 8 illustrates a seventh embodiment of the present invention 400. As shown, the construction of dressing 400 is identical to the first embodiment (FIG. 1) except for slit 410 along one side of frame 408. The dressing of FIG. 8 is useful for securing any tube or line that must enter a sterile field under the membrane 418. The dressing 400 is of particular importance for Hickman catheters, jugular intra-venous lines, central intra-venous catheter dressings and gastrostomy tube dressings.

The slit 410 is incorporated into the frame 408 in order to prevent contaminants from entering the wound site. This is accomplished by using the slit 410 as the channel through which a tube 69 is inserted into the dressing as shown in FIG. 9b. When the tube 69 is placed in the slit, the slit closes along the sides of the tube, sealing the area around the tube 69 from contaminant/moisture seepage into the puncture site. Thus, the use of the slit avoids the drawback of having the dressing 10 lift up as shown in FIG. 9a around the edges of the tube 69. By keeping the wound site sterile, the infection potential about the wound is substantially decreased.

The dressings shown in the various embodiments of the present invention also have the advantage of maintaining an effective barrier to allow for the insertion of various medications and salves, without spillage. Such materials can be contained close to the wound while the dressing and its foam frame enables a patient to shower or even submerge the dressing without affecting such medications.

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The dressing as described in the preferred embodiments is shown in use in a hospital setting. Although, as already pointed out, the dressing may be used in other settings both medical, and non-medical, for holding articles to objects or for securing and sealing objects. For example, one such setting is in the electronics industry where transparent sealing devices may be used to secure wires within, around or between equipment. Another application is in shipping for holding labels to boxes, in dentistry for securing tubes to a patient's mouth, or in packaging for containing spoilable goods in a breathable package.

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What is new and desired to be protected by Letters Patent of the United States is:

WE CLAIM:

1. A transparent dressing for a tracheostomy tube comprising:

a frame having an opening substantially surrounded by said frame;

a transparent non-adhesive membrane positioned below said frame and over said opening wherein a periphery of said frame substantially surrounds said transparent membrane, said membrane having a central aperture for accommodating said tracheostomy tube through said aperture;

an adhesive layer on a bottom surface of said frame such that said membrane is secured to a portion of said frame and said frame portion that extends beyond said membrane forms an adhesive border such that said transparent dressing is adhered to a patient's skin by said adhesive border; and

a pair of ties each having a first end attached to said frame and a second end adapted to attach said tracheostomy tube extending through said central aperture to said frame.

2. The transparent dressing according to claim 1, wherein said frame is formed of a semi-rigid foam material.

3. The transparent dressing according to claim 2, wherein said transparent membrane consists of an air permeable flexible material such that said transparent dressing allows visual observation of such wound.

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4. The transparent dressing according to claim 2, further comprising a liner located below said membrane and attached to said adhesive border such that said liner is adapted to be peeled off of said adhesive border, exposing said adhesive border for contact with such patient's skin.

5. The transparent dressing according to claim 4, wherein said liner consists of a paper material.

6. The transparent dressing according to claim 1, wherein said frame and said transparent membrane are substantially rectangular.

7. The transparent dressing according to claim 1, wherein said frame, and said transparent membrane and opening are substantially circular.

8. The transparent dressing according to claim 1, wherein said central aperture contacts a slit that extends from one edge of said central aperture to an edge of said transparent dressing such that said central aperture can hold said tracheostomy tube to such skin while accommodating curvatures in a patient's neck and still prevent contaminants or liquid from entering a wound site.

9. The transparent dressing according to claim 8, further comprising semi-rigid flexible collar surrounding said tube hole and located on an outer and inner surface of said transparent membrane.

10. The transparent dressing according to claim 9, wherein said collars have respective adhesive surfaces enabling said collars to be adhered to said inner and outer surfaces of said transparent membrane, to a patient's skin and to said tracheostomy tube.

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11. The transparent dressing according to claim 10, wherein said first end of each of said ties includes a loop material and said second end of each of said ties includes a hook material whereby a respective second end is adapted to mate with a respective first end of each of said ties.

12. The transparent dressing according to claim 11, wherein each of said second ends is adapted to loop through a slit located on a collar of said tracheostomy tube and back toward said respective first end of each of said tie thus firmly securing said tracheostomy tube to said transparent dressing.

13. A dressing for a tube, comprising:

a frame member surrounding a window;

a transparent membrane attached to said frame member, and covering said window and having a tube opening for accommodating a tracheostomy tube;

an adhesive border formed on said frame around the perimeter of said transparent membrane such that when adhered to a patient's skin, a chosen area of such skin shows through said membrane covered window opening; and

a pair of ties attached to said frame member wherein each of said ties is adapted to secure said tube to said frame thereby holding said tube in place in said tube opening.

14. The dressing according to claim 13, wherein said frame member incorporates a slit extending from said tube opening to an end of said frame member to prevent lifting up of said

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dressing when said tube is inserted into said dressing and to insure said dressing is sealed around said tube such that contaminants and fluids are prevented from entering said dressing.

15. A dressing for covering a patient's skin comprising:

an outer skin contacting layer having an opening substantially surrounded by said outer layer

a pliable transparent inner skin contacting membrane positioned throughout said opening wherein a perimeter of said outer layer substantially surrounds said membrane; and

an adhesive layer on a bottom surface of said outer layer such that said membrane is secured to a portion of said outer layer and said perimeter of said outer layer forms an adhesive perimeter in order that said dressing is adhered to such patient's skin only at said adhesive perimeter.

16. The dressing according to claim 15, wherein said outer layer is formed of a semi-rigid foam material.

17. The dressing according to claim 16, wherein said transparent membrane consists of an air permeable pliable material such that said dressing allows visual observation of such patient's skin.

18. The dressing according to claim 17, further comprising a liner located below said membrane and attached to said adhesive perimeter, exposing said adhesive perimeter for contact with such patient's skin.

19. The transparent dressing according to claim 18, wherein said flap has a plurality of airholes such that air passes through said flap and through said membrane.

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20. The dressing according to claim 19, wherein said outer layer, said membrane and said opening are rectangular.

21. The dressing according to claim 20, wherein said outer layer, said membrane and said opening are circular.

22. The dressing according to claim 21, wherein said outer layer further comprises a pair of finger portions, each pair extending from opposed ends of said outer layer such that said outer layer forms a substantially "H" shaped dressing.

23. A dressing for a patient's skin, comprising:

an outer layer surrounding a window opening;

a pliable transparent inner skin contacting layer attached to said outer layer and extending throughout said window opening; and

an adhesive border formed on said outer layer around the perimeter of said inner layer such that when adhered to such patient's skin a chosen area of skin shows through said window opening.

24. A method for applying a dressing comprising a pliable transparent membrane attached at its perimeter to a semi-rigid adhesive border having a liner secured to said adhesive border, comprising the steps of:

removing said liner from said adhesive border in order to expose a tacky adhesive surface;

centering said transparent membrane over a wound such that said window contacts such wound; and

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applying said dressing to such wound in order that said tacky adhesive surface substantially contacts skin surrounding such wound rendering such wound entirely visible through said transparent membrane as well as isolated from contact with said semi-rigid adhesive border.

25. A dressing for covering a patient's skin, comprising:

an adhesive frame having an opening substantially surrounded by said adhesive frame; and

a pliable transparent non-adhesive skin contacting membrane attached to said frame and extending throughout said opening where a portion of said adhesive frame extends beyond said membrane and forms an adhesive border to substantially adhere said transparent dressing to such skin at said adhesive border.

26. The dressing according to claim 25, wherein said adhesive frame is formed of a semi-rigid foam material.

27. The dressing according to claim 26, wherein said adhesive frame consists of a single piece of material.

28. The dressing according to claim 27, wherein said adhesive frame substantially retains the shape of said dressing when packaged.

29. The dressing according to claim 28, wherein said transparent membrane consists of an air permeable pliable material such that said dressing allows visual observation of a patient's wound.

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30. The dressing according to claim 29, wherein said transparent membrane is hypo-allergenic allowing the passage of vapor and gases through said transparent membrane in one direction and blocking contaminants and moisture coming into said transparent membrane in a second direction.

31. The dressing according to claim 30, further comprising a liner located on a skin contacting surface of said transparent membrane and attached to said adhesive border such that said liner is adapted to be peeled off of said adhesive border, exposing said adhesive border and transparent membrane to a patient's skin.

32. The dressing according to claim 31, wherein said liner consists of a paper material.

33. The dressing according to claim 32, wherein said adhesive frame is coated with a hypo-allergenic synthetic acrylic pressure sensitive adhesive of sufficient tackiness to seal a wound from liquid and/or air seepage into said dressing.

34. The dressing according to claim 33, wherein a first adhesive is employed to adhere said transparent membrane to said adhesive frame and a second adhesive is employed to adhere said transparent dressing to such patient's skin.

35. A transparent dressing for covering a patient's wound, comprising:

a frame having an opening substantially surrounded by said frame;

a transparent non-adhesive skin contacting membrane positioned below said frame and throughout said opening wherein

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a perimeter of said frame substantially surrounds said transparent membrane;

an adhesive layer on a skin contacting surface of said frame such that said membrane is secured to a portion of said frame and said frame portion that extends beyond said membrane forms an adhesive border enabling said transparent dressing to be adhered to a patient's skin at said adhesive border; and

a flap for substantially covering said opening.

36. The dressing according to claim 35, wherein said flap is formed integrally with said frame.

37. The dressing according to claim 36, wherein said flap is made of a substantially air permeable material.

38. The dressing according to claim 37, wherein said flap has a plurality of air holes such that gas passes through said flap.

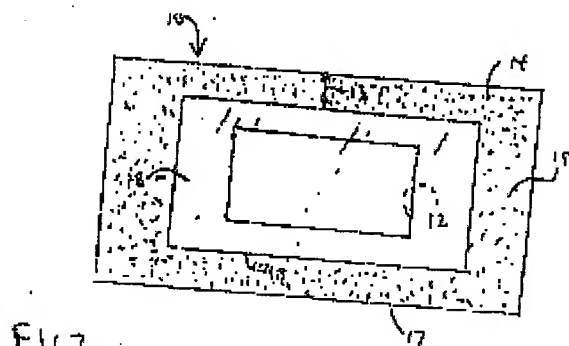
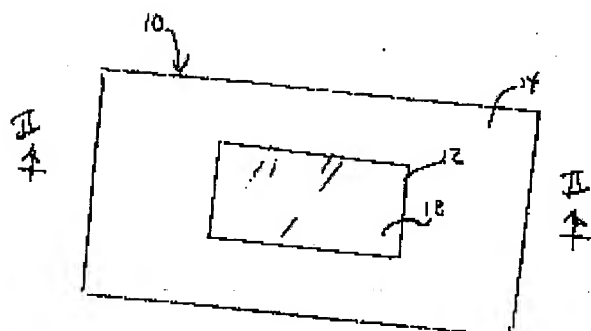
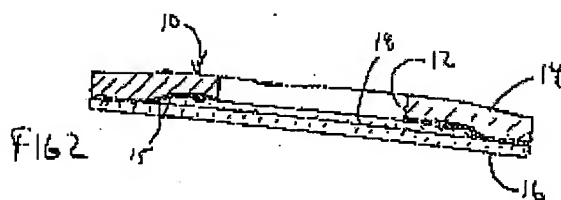
39. The dressing according to claim 38, wherein the perimeter of said flap is larger than the perimeter of said opening.

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ABSTRACT

A transparent dressing for substantially sealing a wound consisting of a semi-rigid frame for defining an opening and a resilient transparent membrane member substantially covering the opening in order to form a transparent window. The transparent material allows air and vapors to permeate the material in a first direction and prevent contaminants and fluids from entering the wound area in an opposite direction. Several embodiments of the invention are shown for firmly holding tracheostomy tubes to the dressing.

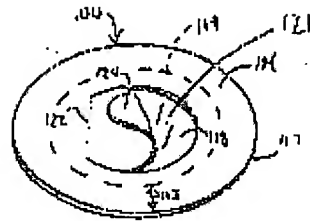
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Patent Agents:

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FIG 4

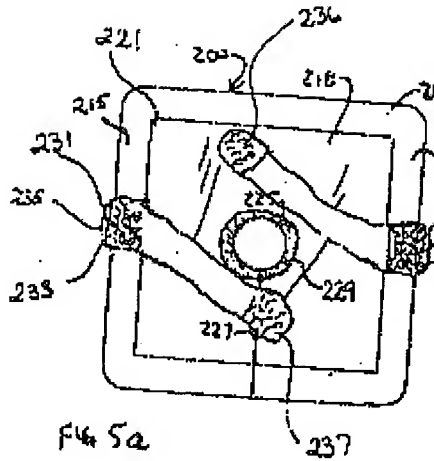


FIG 5a

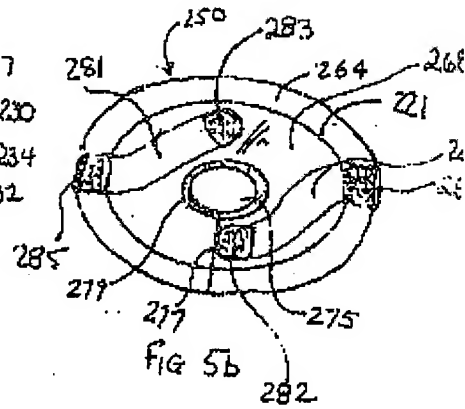


FIG 5b

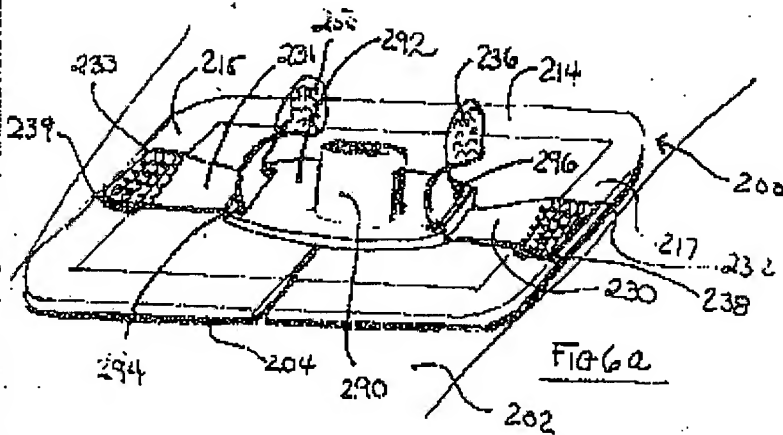


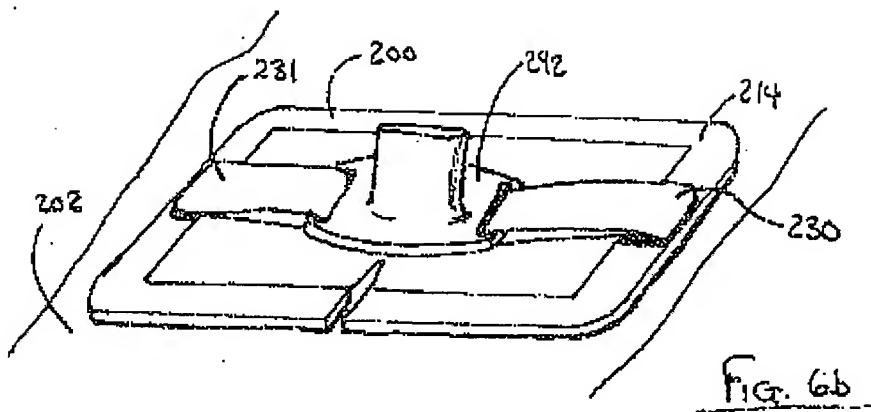
FIG 6a

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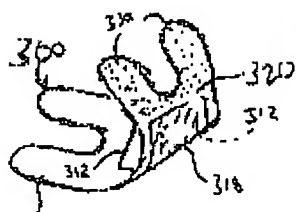


FIG. 7

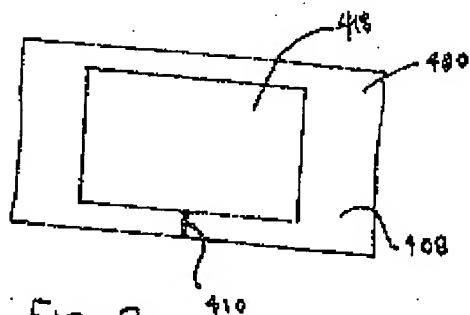


FIG. 8



FIG. 9a

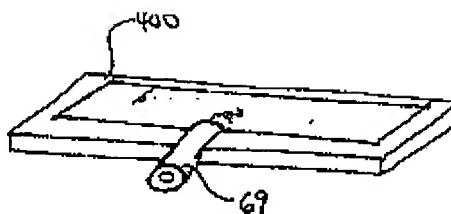


FIG. 9b

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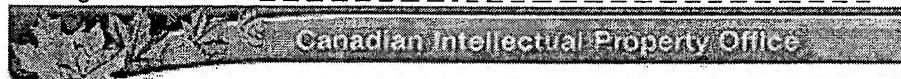
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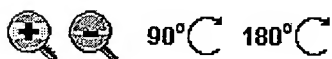
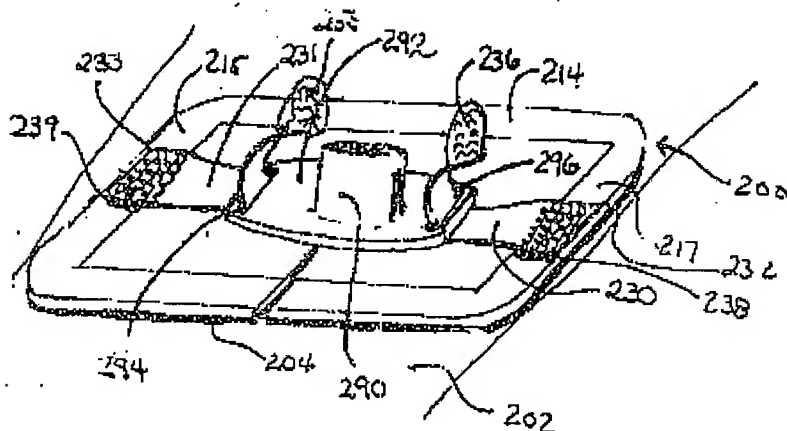
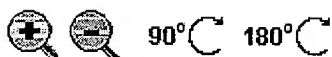


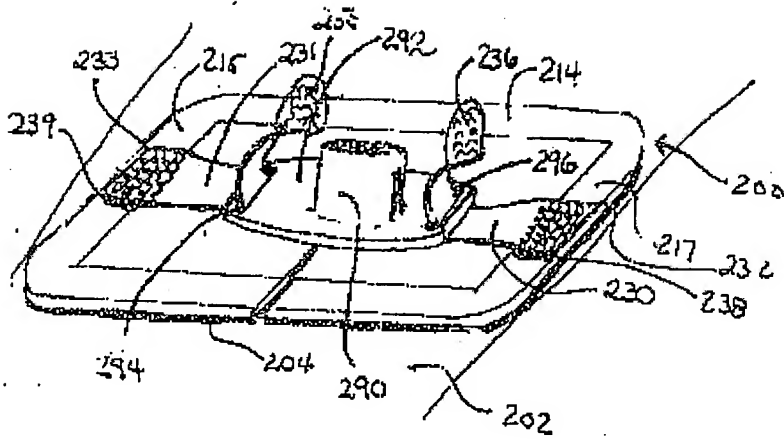
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**A 61 M 1/00**

A 61 M 5/16

①9

**BUNDESREPUBLIK DEUTSCHLAND**

**DEUTSCHES**



**PATENTAMT**

**DE 26 40 413 A 1**

①1

# **Offenlegungsschrift 26 40 413**

②1

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Anmeldetag:

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Bezeichnung:

Katheter-Überwachungsgerät

⑦1

Anmelder:

Richard Wolf GmbH, 7134 Knittlingen

⑦2

Erfinder:

Wurster, Helmut, 7519 Oberderdingen

⑤6

Prüfungsantrag gem. § 28 b PatG ist gestellt

Für die Beurteilung der Patentfähigkeit in Betracht zu ziehende Druckschriften:

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US 39 63 027

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①9 **BUNDESREPUBLIK DEUTSCHLAND**

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**DE 26 40 413 A 1**

stellung jedes negativen Vergleichs ein elektrischer Zählimpuls entwickelt wird, der auf einen Zähler (27) gegeben wird, dessen Endstellung über eine Gatterlogik (32) vorprogrammiert ist, daß der Zähler die unmittelbar nacheinander einlaufenden Zählimpulse zählt und nach Erreichen seiner Endstellung Alarm auslöst und daß der Zähler gelöscht bzw. zurückgestellt wird, sobald er vor Erreichen seiner Endstellung ein aus einem positiven Vergleich entwickeltes Rückstellsignal empfängt.

4. Gerät nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Steuerung des Funktionsablaufes mittels eines Taktgebers (22) erfolgt, der kurz vor Ende jeder Taktzeit (T) einen Impuls (a) zur Durchführung des Vergleichs zwischen dem Ist-Wert und dem Soll-Wert abgibt, nachfolgend einen Impuls (b) zum Entleeren des Meßgefäßes (3) und anschließend einen weiteren Impuls (c) für eine Prüfschaltung (36, 37, 39, 40) liefert, welche die Vollständigkeit der Entleerung des Meßgefäßes überprüft und bei nicht entleertem Meßgefäß ein Alarmsignal auslöst, welches sich vom anderen möglichen Alarmsignal unterscheidet.
5. Gerät nach einem oder mehreren der Ansprüche 1 bis 4, gekennzeichnet durch ein schreibendes und/oder anzeigendes Registriergerät (16), dem das dem Füllvolumen entsprechende Meßsignal wahlweise oder in Kombination direkt, nach Differentiation über einen Differenzierkreis (19) und nach Integration über einen Integrierkreis (18) zwecks Aufzeichnung zugeführt wird.

6. Gerät nach einem oder mehreren der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß das Füllvolumen im Meßgefäß (3) kapazitiv gemessen wird, indem die Kapazität eines Meßkondensators (4, 5) vom zeitabhängigen Füllstand im Meßgefäß beeinflußt und die Kapazitätsänderung zur Erzeugung des Meßsignals ausgewertet wird.
7. Gerät nach Anspruch 6, dadurch gekennzeichnet, daß die eine Kondensatorelektrode (4 oder 5) mit einem Dielektrikum beschichtet ist.
8. Gerät nach einem oder mehreren der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß der Auslauf des Meßgefäßes (3) durch den federbelasteten Stößel (7) eines Magnetventils verschlossen ist, das beim Auftreten des vom Taktgeber (22, 22 b) kommenden Signals zur Entleerung des Meßgefäßes erregt wird, um den Ventilstößel zur Freigabe des Gefäßauslaufes zu betätigen.
9. Gerät nach einem oder mehreren der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß es zu Reinigungszwecken zumindest teilweise demontierbar ist.

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### Katheter-Überwachungsgerät

Die Erfindung betrifft ein Gerät zur Überwachung der aus einem Katheter austretenden Körperflüssigkeit, bei dem unter Verwendung eines Meßgefäßes die Körperflüssigkeit aufgefangen und das Füllvolumen gemessen wird, um hieraus ein dem Füllvolumen entsprechendes elektrisches Meßsignal zu entwickeln.

Nach Operationen bzw. endoskopischen Eingriffen in der Niere und der Blase werden postoperativ Katheter eingelegt, um den Urin direkt abzuleiten. Hierbei ist es wichtig, daß eine bestimmte Urinmenge pro Zeiteinheit abgeht und daß beim Verstopfen oder Abklemmen des Katheters das Pflegepersonal alarmiert wird, um die Ursache der Störung zu beseitigen.

Es sind Überwachungsgeräte bekannt, bei denen die Körperflüssigkeit aus dem Katheter in ein Gefäß mit einem engen Auslaß geleitet wird, aus dem die Flüssigkeit tropfenweise austritt, wobei die Tropfen zwei oder mehr mit geringem Abstand zueinander liegende Elektroden kurzzeitig überbrücken. Dieser Vorgang wird elektrisch zur Steuerung einer Signalschaltung herangezogen, indem etwa ein zeitlich über-

mäßig langes Ausbleiben von Tropfen bzw. Elektrodenüberbrückungen einen Alarm zur Folge hat.

Diese Geräte haben sich allerdings in der Praxis nicht bewährt, da sie im Aufbau zu aufwendig und stör anfällig sind. Außerdem bereitet die Reinigung der Geräte meist Schwierigkeiten.

Die Aufgabe der Erfindung besteht in der Beseitigung dieser Nachteile und insbesondere in der Schaffung eines Überwachungsgerätes, bei dem über ein elektrisches Warnsystem eine beliebige Einstellung der Alarmschwelle möglich ist.

Zu diesem Zweck wird das eingangs erwähnte Gerät nach der Erfindung so ausgebildet, daß in einem vorgegebenen Meßtakt das Meßsignal als Ist-Wert mit einem Soll-Wert vergleichbar ist, der den bei einer normalen Körperfunktion in der Taktzeit zu erwartenden Füllvolumen zugeordnet ist, daß bei einem negativen Vergleich, also wenn der Ist-Wert nicht mit dem Soll-Wert übereinstimmt, mittels einer Alarmeinrichtung ein Alarmsignal erzeugt wird und daß das Meßgefäß nach jedem Meßtakt automatisch entleert wird.

Zweckmäßigerweise kann die Alarmeinrichtung so vorprogrammiert werden, daß das Alarmsignal erst nach Ablauf einer einstellbaren Anzahl von Meßtakten gegeben wird, falls das Meßsignal den Soll-Wert während dieser Meßtakte nicht erreicht hat. Auf diese Weise wird eine unnötige Alarmgabe vermieden, falls sich im Laufe der eingestellten

Meßtakte die Körperfunktion des Patienten wieder normalisiert hat oder wenn es sich nur um eine unschädliche vorübergehende Störung des Gerätes gehandelt hat.

Aus der Feststellung jedes negativen Vergleichs wird ein elektrischer Zählimpuls erzeugt, der auf einen Zähler gegeben wird, dessen Endstellung über eine Gatterlogik programmierbar ist. Dieser Zähler zählt die unmittelbar nacheinander einlaufenden Zählimpulse und löst nach Erreichen seiner vorgewählten Endstellung Alarm aus. Andernfalls wird der Zähler gelöscht bzw. zurückgestellt, sobald er vor Erreichen seiner Endstellung ein Rückstellsignal empfängt, das bei einem positiven Vergleich des Ist-Wertes mit dem Soll-Wert entwickelt wird.

Das Füllvolumen im Meßgefäß wird kapazitiv gemessen, indem die Kapazität eines Kondensators vom zeitabhängigen Füllstand der Körperflüssigkeit beeinflußt und die Kapazitätsänderung zur Erzeugung des Meßsignals elektrisch ausgewertet wird.

In der anliegenden Zeichnung ist ein Ausführungsbeispiel der Erfindung dargestellt. Es zeigen:

Figur 1 die Seitenansicht des mechanischen Geräteaufbaues in teilweise Längsschnitt und

Figur 2 schematisch die elektrische Schaltung des Überwachungsgerätes.

Die Körperflüssigkeit gelangt gemäß Figur. 1 vom Katheter des Patienten über den Schlauch 1 zu einem Einlauftrichter 2 und von diesem aus in das Meßgefäß 3. In diesem sind zwei getrennte Elektroden 4, 5 vorgesehen, die einen Meßkondensator bilden und von denen eine mit einem Dielektrikum 5 a beschichtet ist, so daß die Körperflüssigkeit nur leitenden Kontakt mit der anderen Elektrode haben kann.

Durch die in das Gefäß 3 einfließende Flüssigkeit ändert sich wegen des direkten Kontaktes der Körperflüssigkeit mit einer Elektrode die Geometrie des Meßkondensators 4, 5 und somit die Kapazität, und zwar in direkter Abhängigkeit vom jeweiligen Füllstand und Füllvolumen im Meßgefäß. Auf an sich bekannte Weise wird in einem Meßspannungsgeber 6 aus der Kapazitätsänderung eine Spannungsänderung erzeugt, die als Meßspannung zur Verfügung steht und der zeitlichen Volumenfunktion entspricht.

Das Meßgefäß 3 ist am unteren Auslauf mit einem Stößel 7 verschlossen, der als Dauermagnet 8 mit einem Mantel 9 aus Kunststoff ausgebildet ist. Im übrigen ist der im Raum 10 axial geführte und mit einer Feder 11 abgestützte Stößel 7 außen von einer Wicklung 12 umgeben, die als Magnetwicklung zusammen mit dem Stößel ein Magnetventil bildet.

Wie noch später näher zu erläutern ist, wird der Stößel 7 bei Erregung des Magnetventils gegen die Wirkung der Feder 11 nach unten gezogen, um den Auslauf des Gefäßes 3 freizugeben und die Körperflüs-

sigkeit in den Schlauch 13 abfließen zu lassen. Zweckmäßigerweise sollte zumindest das Innenrohr 14, der Stößel 7 mit der Feder 11 sowie das Gefäß 3 mit den Elektroden 4, 5 zu Reinigungszwecken leicht ausgebaut werden können.

Der schaltungstechnische Aufbau des Gerätes geht aus der Figur 2 hervor. Der Meßspannungsgeber 6 gibt eine dem augenblicklichen Füllvolumen im Gefäß 3 entsprechende Spannung als Meßsignal auf die Leitung 15. Ein schreibendes und anzeigendes Registriergerät 16 kann das Meßsignal direkt über die Leitung 17 aufnehmen, um so die unmittelbar abgehende Körperflüssigkeit als Volumen registrieren zu können. Hierdurch kann man sich beispielsweise ein Bild darüber verschaffen, wie gleichmäßig die Nieren Urin ausscheiden.

Weiterhin kann das Meßsignal über einen Integrierkreis 18 zum Gerät 16 geleitet werden, um die gesamte Menge der in das Gefäß 3 geflossenen Flüssigkeit registrieren zu lassen. Schließlich ist auch noch ein Differenzierkreis 19 vorgesehen, in dem das Meßsignal differenziert wird und dessen Ausgangssignal dann die zeitliche Strömungsrate darstellt, die ebenfalls im Gerät 16 zur Registrierung kommt.

Eine Aussage darüber, ob ein Patient ausreichend Körperflüssigkeit ausscheidet, läßt sich dadurch erzielen, daß man das in einer bestimmten Zeit im Gefäß 3 angesammelte Füllvolumen als Ist-Wert in Vergleich setzt zu einem Soll-Wert, der bei einer normalen oder einer

auf den jeweiligen Behandlungsfall abgestellten Körperfunktion an sich erwartet werden muß.

Für das Füllvolumen steht eine Vergleichsgröße durch das vom Meßgeber 6 kommende Meßsignal als Spannung auf der Leitung 15 zur Verfügung. Diese Spannung gelangt auf einen Eingang eines Differenzverstärkers 20. Der Soll-Wert wird am Stellwiderstand 21 vorprogrammiert und auf den anderen Eingang des Verstärkers 20 gegeben.

Die einzuhaltende Meßzeit wird von einem Taktgeber 22 bestimmt, dem ein Impulsgeber 22 a zugeordnet ist. Dieser erzeugt innerhalb der gesamten Taktzeit T einen Impuls a, der zur Einleitung des Vergleichs zwischen dem tatsächlichen Füllstand im Gefäß 3 als Ist-Wert und dem am Widerstand 21 eingestellten Soll-Wert auf die Leitung 23 gegeben wird.

Wenn der Ist-Wert den Soll-Wert erreicht hat und damit der Vergleich positiv ausfällt, ist am Ausgang des Differenzverstärkers 20 ein Ausgangssignal vorhanden, das an einem Eingang des Tores 24 ansteht, während der andere Eingang dieses Tores mit dem Impuls a beaufschlagt wird. Bei diesem Betriebszustand wird am Ausgang des Tores 24 ein Rückstellimpuls entstehen, der über die Leitung 26 einen Zähler 27 auf "0" stellt mit der Folge, daß die nachgeschaltete Alarmanrichtung 28 kein Signal gibt.

Wenn andererseits am Tor 24 kein Ausgangsimpuls entsteht, also wenn

der Vergleich zwischen Ist-Wert und Soll-Wert negativ ausgefallen ist, erzeugen während der Meßzeit der Inverter 29 und das Tor 30, an dessen einem Eingang ebenfalls der Impuls a liegt, einen Zählimpuls, der über die Leitung 31 auf den Eingang des Zählers 27 gelangt und diesen um eine Zählstellung weiterstellt. Wie noch nachfolgend beschrieben wird, würde bei dieser Zählerstellung eine Alarmgabe ausgelöst, wenn die Endstellung des Zählers 27 auf "1" programmiert ist.

Die jeweiligen Endstellungen des Zählers werden mit einer Gatterlogik 32 programmiert. Beispielsweise könnte die Endstellung auf "4" eingestellt werden, wie es auch in der Zeichnung dargestellt ist. Hieraus wird folgen, daß insgesamt vier Zählimpulse nacheinander über die Leitung 31 in den Zähler 27 einlaufen müßten, bevor dieser in die vorprogrammierte Endstellung "4" gelangt und über die Leitung 33 ein Alarmsignal zur Alarmeinrichtung 28 gibt, die hierdurch in Betrieb gesetzt wird. Auf diese Weise hätte man im Vergleich zu einer Zählerendstellung "1" eine Zeitvorgabe von vier Meßtakten bis zu einer Alarmauslösung für den Fall, daß nacheinander vier negative Vergleiche ermittelt werden und damit auch vier Zählimpulse auf der Leitung 31 ankommen. Dies bringt insofern Vorteile, als eine kurzzeitige unschädliche Störung oder ein nur vorübergehend ungenügender Fluß von Körperflüssigkeit keine unnötige Alarmgabe verursachen wird, da bei einem wieder positiven Vergleich während der Zeit von vier Takten und vor Erreichen der Zählerendstellung über die Leitung 26 das Zähler-

rückstellsignal kommen wird.

Zum Taktgeber 22 gehört ein weiterer Impulsgeber 22 b, der nach Durchführung des vorher beschriebenen Meßvorganges einen Impuls b über die Leitung 34 zur Wicklung 12 des Magnetventils gibt, um durch Einwirkung des sich aufbauenden Magnetfeldes den Stößel 7 von der Auslauföffnung des Gefäßes 3 abzuheben und dieses leerlaufen zu lassen. Nach Beendigung dieses Steuerimpulses wird der Magnet entregt, und die Feder 11 drückt den Stößel 7 auf seinen Sitz zurück.

Um kontrollieren zu können, ob das Gefäß 3 vor dem nächsten Meßtakt und Meßvorgang vollständig entleert ist, wird in der zum Taktgeber 22 gehörenden Schaltung 22 c ein Impuls c entwickelt, der auf die Leitung 35 und zunächst an den einen Eingang eines Tores 36 gelangt. Am anderen Eingang dieses Tores ist der Ausgang eines Verstärkers 37 angeschlossen, der über die Leitungen 15 und 38 mit dem Meßsignal gespeist wird.

Wenn das Gefäß 3 während der Dauer des Impulses c leer ist, entsteht am Ausgang des Tores 36 ein Impuls. Dieser wird über den Inverter 39 und das Tor 40 gedreht, an dem ebenfalls der Impuls c über die Leitung 41 ansteht. Dies hat zur Folge, daß kein Alarmsignal auf der Leitung 42 zur Alarmeinrichtung 28 kommen wird. Wenn dagegen das Meßgefäß 3 nicht völlig leer ist, entsteht am Ausgang des Tores 40 ein Alarmimpuls, der die Alarmeinrichtung 28 in Betrieb setzt, um einen technischen Fehler des Gerätes anzuzeigen.

Das Signal, das einen solchen Fehler anzeigt, soll sich von dem Signal, das ein ungenügendes Füllvolumen anzeigt, eindeutig unterscheiden, damit das Pflegepersonal sofort erkennen kann, wo eine Störung gegeben ist und wo eine Prüfung stattzufinden hat. Das eine Signal kann also beispielsweise akustisch mit dem Lautsprecher 43 und das andere Signal optisch mit der Lampe 44 erzeugt werden. Andererseits könnte man auch nur mit Lampen oder Lautsprechern bzw. akustischen Signalgebern arbeiten, wenn man die Unterscheidung durch unterschiedliche Lichtfarben oder sich stark voneinander abhebende Tonhöhen bzw. Tonpegel gewährleistet.

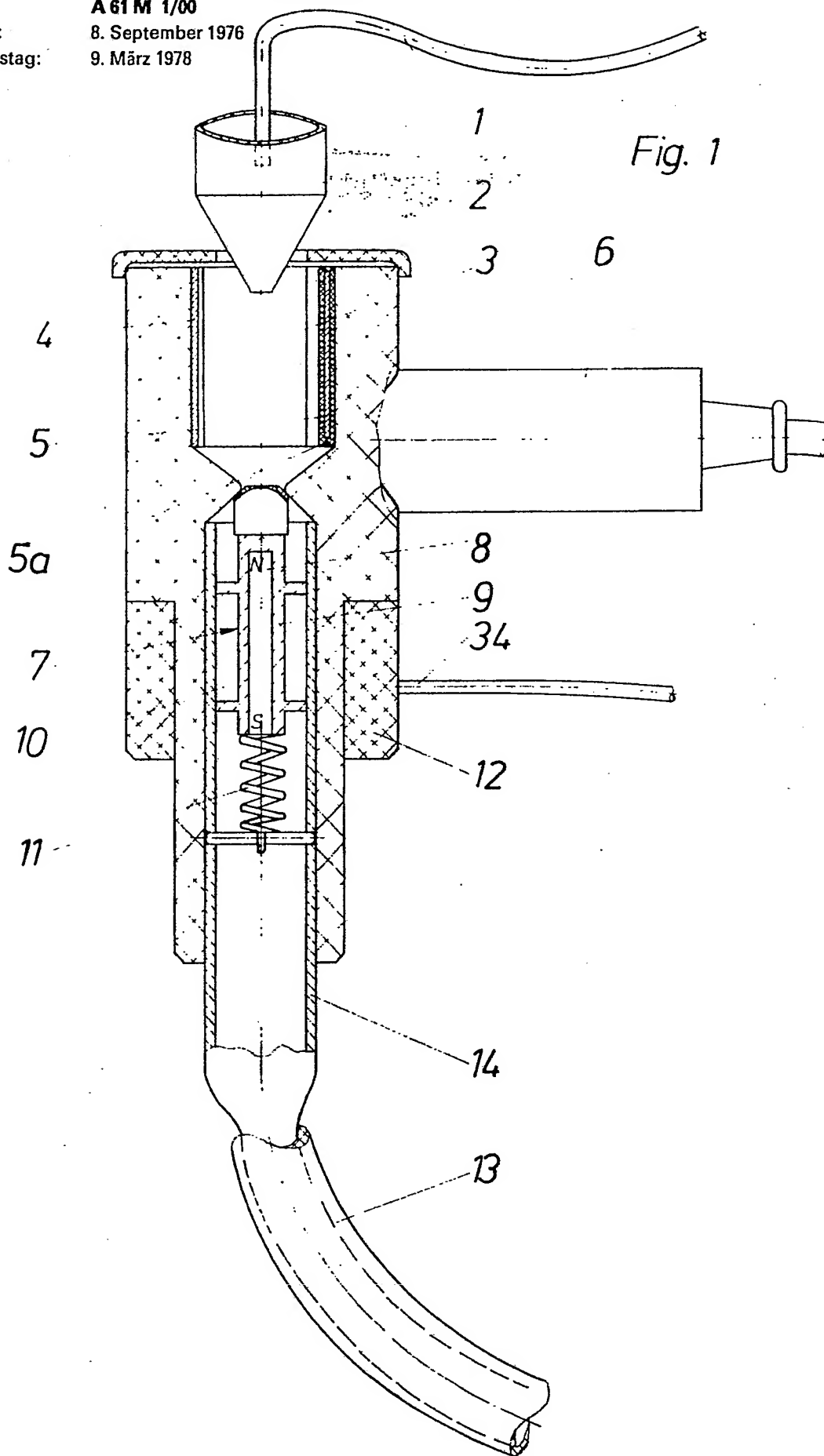
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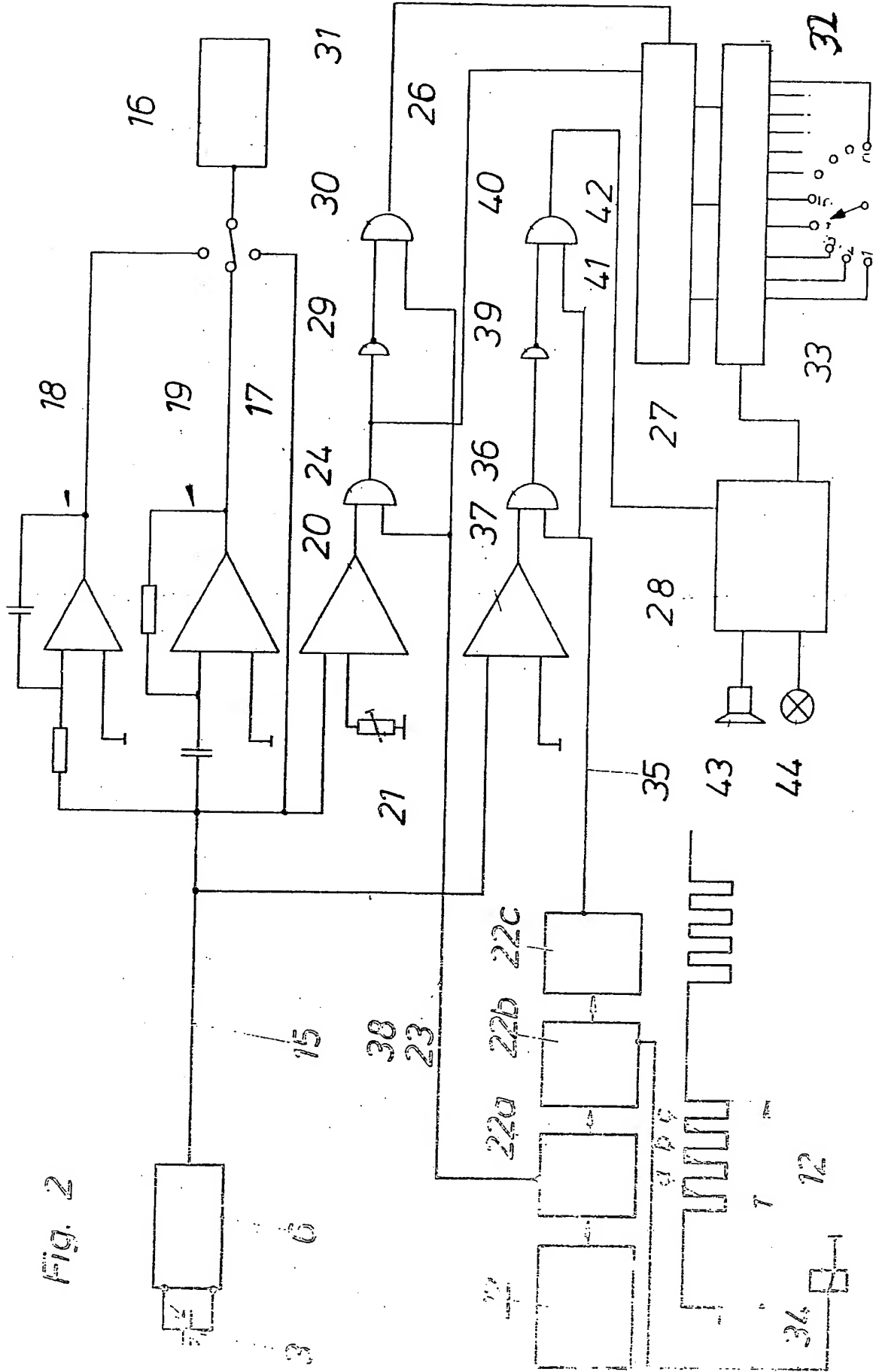


Fig. 2

**DEVICE FOR MONITORING BODY LIQUID COMING FROM A CATHETER****Patent number:** DE2640413**Publication date:** 1978-03-09**Inventor:** WURSTER HELMUT**Applicant:** WOLF GMBH RICHARD**Classification:****- international:** **A61B5/20; A61M25/00; G01F23/26; A61B5/20;  
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Der Inhalt dieser Schrift weicht von den am Anmeldetag eingereichten Unterlagen ab

54 Drainagevorrichtung, insbesondere Pleuradrainagevorrichtung, und Drainageverfahren

57 Die Erfindung betrifft eine Drainagevorrichtung zum Absaugen von Fluiden aus einer Körperhöhle, insbesondere der Pleurahöhle (12), mit einem Drainageschlauch (52) zum Absaugen der Fluide und einer Einrichtung (84) zum Ausbilden eines Unterdrucks in der Körperhöhle. Erfindungsgemäß ist eine Zusatzleitung (54) vorgesehen, deren Lumen am patientenseitigen Ende in Fluidverbindung mit dem Lumen des Drainageschlauchs (52) steht, und über die der Körperhöhle ein Gas zugeführt wird. Mit der erfindungsgemäßen Drainagevorrichtung können Störungen bei der Drainage vermieden und die Durchgängigkeit des Drainagesystems sichergestellt werden.

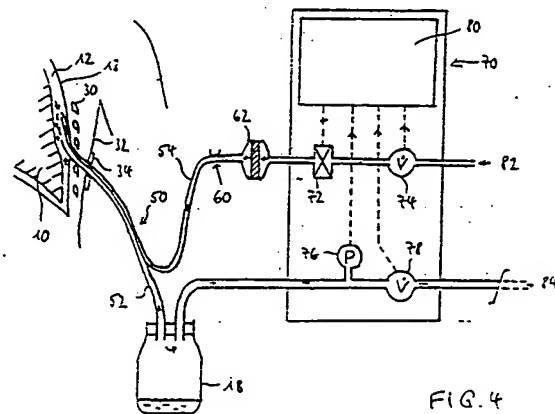


FIG. 4

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## Beschreibung

Bei der herkömmlichen Drainage bzw. dem Absaugen von Fluiden aus einer Körperhöhle, insbesondere der Pleurahöhle, wird üblicherweise ein einlumiger Schlauch verwendet, der mittels eines Trocars oder operativ in die Körperhöhle verbracht wird. Durch Anschluß des Schlauchs an eine Unterdruckquelle wird Fluid, wie Luft oder Flüssigkeit, aus der Körperhöhle abgesaugt.

Die meisten herkömmlichen Drainagesysteme für Körperhöhlen erlauben keine Messung der Strömungsgeschwindigkeit. Oft ist nicht einmal eine Anzeige vorhanden, ob überhaupt eine Strömung aus der Körperhöhle vorliegt. Es sind allerdings auch Konstruktionen bekannt, bei welchen die Strömung angezeigt wird, zum Beispiel dadurch, daß der abgesaugte Gasstrom durch eine Flüssigkeit geführt wird, wobei das Vorliegen einer Strömung durch aufsteigende Blasen angezeigt wird.

Andererseits ist eine quantitative Angabe sowohl über die initiale als auch über die eventuell fortlaufend abgesaugte Gas- oder Flüssigkeitsmenge eine klinisch wichtige Information. So kann beispielsweise bei einer fortbestehenden Leckage zwischen dem Bronchialsystem und dem Pleuraraum aus der Menge des pro Minute in die Pleurahöhle nachströmenden Atemgases beurteilt werden, ob ein spontaner Verschuß der Leckage zu erwarten ist, oder ob ein operatives Vorgehen erwogen werden sollte.

Eine exakte Messung der Menge abgesaugter Fluide wäre auch deshalb wünschenswert, weil der optimale Unterdruck im Drainagesystem nur per Durchflußmessung bestimmt werden kann. Optimal ist der Unterdruck bzw. Sog dann, wenn eine maximale Gas- oder Flüssigkeitsmenge pro Zeitintervall abgesaugt wird. Dies ist nicht notwendigerweise ein möglichst hoher Sog, denn ein zu hoher Sog führt oft zu einem Haften von anatomischen Strukturen, z. B. peripheren Lungenanteilen bei der Pleuradrainage, oder Gerinnseln an den Saugöffnungen des Schlauchs und somit zu einem Verschuß der Drainage.

Die herkömmlichen Drainagesysteme sind auch stör anfällig. So vermindert beispielsweise Flüssigkeit, die in durchhängenden Teilen des Schlauches liegt, den patientenseitigen Unterdruck oder hebt ihn ganz auf. Dasselbe gilt für im Schlauch geronnene Flüssigkeit und für Knickstellen. Derartige Störungen treten häufig auch im nichteinsehbaren Teil des Drainagesystems von der Verbandabdeckung bis zur Körperhöhle, beispielsweise zum Thoraxinnenraum, auf und sind deshalb nur schwer erkennbar. Es kann sich dann immer noch oder gegebenenfalls erneut Gas oder Flüssigkeit in der Körperhöhle des Patienten ansammeln. Einen Hinweis darauf können nur gründliche Untersuchungsverfahren, wie Auskultation (Abhören) oder Röntgen, geben. Wenn derartige Probleme nicht rechtzeitig erkannt werden, können auch kritische Symptome seitens des Patienten auftreten.

Der Erfindung liegt somit die Aufgabe zugrunde, eine Drainagevorrichtung zum Absaugen von Fluiden aus einer Körperhöhle bereitzustellen, mit der die vorstehenden Probleme vermieden werden können und ein störungsfreier Verlauf der Drainage sichergestellt wird, insbesondere die Durchgängigkeit des Drainagesystems einfach sichergestellt und überwacht werden kann.

Diese Aufgabe wird durch die Merkmale der Patentansprüche gelöst. Die Erfindung geht dabei von dem Grundgedanken aus, einen doppelläufigen Schlauch

bzw. eine doppelläufige Sonde bereitzustellen, wobei ein größeres Lumen des Schlauchs dem Absaugen von Fluiden aus einer Körperhöhle und ein kleineres Lumen des Schlauchs der permanenten oder intermittierenden Zufuhr eines Gases in die Körperhöhle dient, so daß praktisch eine Durchspülung der Körperhöhle stattfinden kann.

Die Erfindung wird nachstehend anhand einer Pleuradrainage näher erläutert. Das erfindungsgemäße Prinzip der Doppelläufigkeit mit ausreichender Kontrolle und Erhaltung der Durchgängigkeit des Systems sowie gegebenenfalls einer Differenzbestimmung der Strömung in den beiden Lumen der Sonde ist aber auch bei anderen chirurgischen Drainagen anwendbar, z. B. im Bauchraum, in Gelenken und bei urologischen Eingriffen, die mit Spülmaßnahmen verbunden sind.

Erfindungsgemäß ist neben einem zum Unterdrucksystem führenden Drainageschlauch eine zweite Leitung bzw. Zusatzleitung vorgesehen, die am patientenseitigen Ende, wo sich die Absaugöffnung des Drainageschlauchs befindet, mit dem Lumen des Drainageschlauchs verbunden ist. Vorzugsweise weist hierzu der Drainageschlauch selbst ein zweites Lumen bzw. eine zweite Lichtung auf, die die Zusatzleitung bildet. Die Zusatzleitung kann im Vergleich zum Drainageschlauch einen relativ kleinen Querschnitt aufweisen. Vorzugsweise ist die Zusatzleitung über einen Bakterienfilter, einen Durchflußmesser und ein Sicherheitssperrenteil mit der Außenluft verbunden. Außerdem ist, vorzugsweise patientenseitig vom Bakterienfilter, ein Zuspritzventil angeordnet, über das beispielsweise Flüssigkeiten zum gelegentlichen Freispülen oder Medikamente, wie Lokalanästhetika oder Antibiotika, in das System eingebracht werden können.

Der Drainageschlauch, der den absaugenden Schenkel der Leitung bildet, führt in der Regel, wie bisher üblich, in ein Abscheidegefäß. Das Abscheidegefäß ist, vorzugsweise über einen weiteren Durchflußmesser, mit einer Unterdruckquelle verbunden. Die Unterdruckquelle kann in bekannter Weise Einrichtungen zur Unterdruckmessung, zur Vermeidung einer Strömungsumkehr und/oder Störungsalarmeinrichtungen, aufweisen.

Im Betrieb der erfindungsgemäßen Drainagevorrichtung strömt einerseits ein Gas, vorzugsweise Luft, über die Zusatzleitung in die Pleurahöhle, während andererseits die abgesaugten Fluide aus der Pleurahöhle ausströmen. Das erfindungsgemäße Meßprinzip besteht darin, die Differenz zwischen dem Zufluß und dem Abfluß der Pleurahöhle zu messen. Vorzugsweise wird diese Differenz über ein bestimmtes Zeitintervall integriert. Aus dieser Differenz läßt sich dann einerseits die Höhe der geförderten Fluidmenge zu Beginn der Drainage und andererseits die Menge des bei weiterbestehender Leckage kontinuierlich oder phasisch in die Pleurahöhle austretenden Atemgases ermitteln.

Das Vorliegen einer Strömung in beiden Leitungen, d. h. der Zusatzleitung und dem Drainageschlauch, zeigt die Durchgängigkeit an. Diese Strömung, die auch ohne patientenseitigen Beitrag besteht, sorgt für eine ständige Entleerung anfallender Flüssigkeiten aus dem Schlauchsystem in das Abscheidegefäß.

Die erfindungsgemäße Drainagevorrichtung kann kontinuierlich betrieben werden. Vorzugsweise kann die Drainagevorrichtung aber auch so betrieben werden, daß die Zusatzleitung bzw. der zuführende Schenkel intermittierend geöffnet wird. Ist die Zusatzleitung gesperrt, reduziert sich die Differenz der beiden Durch-

flüsse auf die Strömung im abführenden Teil (Drainageschlauch), die dann unmittelbar das vom Patienten kommende Fluidvolumen pro Zeiteinheit ergibt. Das intermittierende Öffnen der Zusatzleitung dient einerseits der Durchspülung, d. h. dem Absaugen von Flüssigkeit, und andererseits der Kontrolle, ob das Drainagesystem weiterhin durchgängig ist. Beim intermittierenden Betrieb wird beim Schließen der Zusatzleitung zunächst Flüssigkeit eingesaugt, die dann beim Öffnen abgesaugt wird, da kein Sogausgleich stattfindet. Außerdem kann beim intermittierenden Betrieb die Gefahr verringert werden, daß es beim Ansaugen von unbefeuchteter Luft zu einer Austrocknung von anatomischen Strukturen kommt, die in der Nähe der Absaugöffnungen, d. h. am pleuralen Ende der Sonde liegen.

Bei der erfindungsgemäßen Drainagevorrichtung ist vorzugsweise vorgesehen, daß im Fall einer negativen Differenz zwischen Abfuhr und Zufuhr, d. h., daß in dem zuführenden Schenkel der Zusatzleitung eine höhere Strömung herrscht als im abführenden Schenkel des Drainageschlauchs, die Zusatzleitung automatisch gesperrt wird, um eine Gasvermehrung im Pleuraraum zu verhindern.

In einer weiteren Ausführungsform der Erfindung ist eine wahlweise Zuschaltung der Zusatzleitung vorgesehen. Die Anwendung einer derartigen Drainagevorrichtung ist beispielsweise dann vorteilhaft, wenn bei zunächst unkompliziertem Krankheitsverlauf keine aufwendigen Meßvorrichtungen erforderlich sind, die Drainagevorrichtung bei Bedarf aber jederzeit ergänzt werden kann. Bei dieser Ausführungsform ist zwischen dem Zuspitzventil und dem Bakterienfilter ein Unterdruckmanometer in die Zusatzleitung geschaltet und stromaufwärts vom Bakterienfilter, d. h. im patientenfernen Teil der Zusatzleitung, ist ein Belüftungsventil vorgesehen. Ferner ist die Zusatzleitung an ihrem Ende mittels einer abnehmbaren Kappe verschlossen. Nach Abnehmen dieser Kappe kann die Drainagevorrichtung in dieser Ausführungsform um eine Meßvorrichtung erweitert werden.

Im Betrieb der Drainagevorrichtung in dieser Ausführungsform zeigt das Manometer bei fehlendem Gas- bzw. Flüssigkeitszufluß aus dem Thoraxraum einen Unterdruck an, der mit dem vor der Drainage anliegenden Unterdruck identisch ist. Bei Zufluß aus dem Thoraxraum zeigt das Manometer dagegen den Druck in der Pleurahöhle an, also einen geringeren Druck. Die Druckdifferenz zeigt somit eine Strömung aus dem Pleuraraum in die Saugung an, und bei bekanntem Leitungswiderstand kann daraus dann das Strömungsvolumen pro Zeitintervall bestimmt werden. Ein bekannter Leitungswiderstand ist dann anzunehmen, wenn eine Einengung oder Verlegung des Systems ausgeschlossen werden kann.

Beim Betätigen (Öffnen) des Belüftungsventils in der Zusatzleitung wird der Unterdruck im ansaugenden Schenkel (Zusatzleitung) abgebaut und die im abführenden Schenkel (Drainageschlauch) liegende Flüssigkeit wird in das Abscheidegefäß entleert. Wird danach das Belüftungsventil wieder geschlossen, erreicht der durch das Manometer angezeigte Unterdruck im ansaugenden Schenkel im Normalbetrieb wieder den vorherigen Wert. Ein Verbleiben der Anzeigen des Manometers auf dem Wert, der bei geöffnetem Belüftungsventil angezeigt wurde, oder eine verlangsamte Druckverringering zeigt hingegen eine teilweise oder vollständige Verlegung des Systems an. In diesem Fall kann dann versucht werden, durch Zuspitzen von steriler Spülflüs-

sigkeit, beispielsweise physiologischer NaCl-Lösung, und mehrmaliges Betätigen des Belüftungsventils das System wieder durchgängig zu machen. Hingegen ist bei der herkömmlichen Pleuradrainage mit einlumiger Sonde im Falle einer derartigen Störung regelmäßig das Anlegen einer neuen Drainagesonde, d. h. ein neuerlicher operativer Eingriff, erforderlich.

Die Erfindung wird nachstehend anhand der Zeichnungen näher erläutert. Es zeigt

Fig. 1 das patientenseitige Ende einer erfindungsgemäßen doppelläufigen Drainagesonde,

Fig. 2a, b einen Querschnitt der erfindungsgemäßen Drainagesonde sowie einen Mandrin zur Einbringung der Sonde in den Pleuraraum,

Fig. 3 eine vergrößerte Darstellung der erfindungsgemäßen Drainagesonde,

Fig. 4 eine Ausführungsform der erfindungsgemäßen Drainagevorrichtung,

Fig. 5 eine weitere Ausführungsform der erfindungsgemäßen Drainagevorrichtung mit ankoppelbaren Meßeinrichtungen,

Fig. 6 eine herkömmliche Pleuradrainage (Thoraxdrainage) nach Bülow, und

Fig. 7 verschiedene Störungsmöglichkeiten bei der herkömmlichen Pleuradrainage gemäß Fig. 6.

Bei der Darstellung der herkömmlichen Pleuradrainage nach Bülow in Fig. 6 ist mit 10 die Lunge des Patienten, mit 12 die Pleurahöhle (Pleuraraum) und mit 13 das Rippenfell (Pleura parietalis) bezeichnet. Der Drainageschlauch (Drain) 14 ist mit seiner Ansaugöffnung 16 in die Pleurahöhle 12 des Patienten eingelegt. Die Pfeile im Drainageschlauch 14 geben die Strömungsrichtung an. Ein Flüssigkeitsabscheidegefäß 18 nimmt Ergußflüssigkeit, Blut etc. auf. Eine Durchflußmeßvorrichtung (Flowkontrolle) 20 zeigt das Vorhandensein einer Strömung, d. h. den aktuellen Abtransport eines Fluides, wie Gas oder Flüssigkeit, aus der Pleurahöhle 12 des Patienten an, wenn in einer in der Durchflußmeßvorrichtung enthaltenen Flüssigkeit 21 Blasen aufsteigen. Ein Wasserschloß 22 dient als Druckregelung und begrenzt durch den Einstrom von atmosphärischer Luft durch das mittlere Rohr des Wasserschlosses 22 den Unterdruck auf die durch die Eintauchtiefe des mittleren Rohrs gegebene Höhe. Der Unterdruck wird durch eine Saugpumpe 24 erzeugt und an einem Manometer 26 gemessen. Die drei Einheiten 18, 20 und 22 sowie das Manometer 26 können auch in einer einzigen Überwachungsvorrichtung zusammengefaßt sein.

Fig. 7 zeigt verschiedene Störungsmöglichkeiten an einer herkömmlichen Pleuradrainage gemäß Fig. 6. Dabei sind die Rippen des Patienten mit 30, die Haut mit 32 und ein Verband mit 34 bezeichnet. Bei 36 und 37 kann eine Verlegung der Drainage durch anliegende Lunge oder Rippenfell oder durch geronnene Flüssigkeit im Pleuraspalt auftreten. Bei 38 kann eine Verlegung durch Abknickung oder geronnene Flüssigkeit auftreten. Bei 39 kann schließlich eine Verlegung durch Flüssigkeit in einem durchhängenden Schlauchabschnitt auftreten. Dabei ist zu beachten, daß die Grenze der optischen Kontrollmöglichkeit durch den Verband 34 gegeben ist, so daß beispielsweise die Verlegungen bei 36, 37 und 38 durch optische Kontrolle nicht erkannt werden können. Allerdings werden in der Praxis auch Verlegungen durch Flüssigkeiten in durchhängenden Schlauchabschnitten, wie bei 39, nicht immer rechtzeitig erkannt.

Fig. 1 zeigt das patientenseitige Ende eines erfindungsgemäßen doppelläufigen Drains 50. Dabei sind in Fig. 1 gleiche Teile mit den gleichen Bezugszeichen wie

in den Fig. 6 und 7 bezeichnet.

Fig. 2a und 2b zeigen eine Möglichkeit der Einbringung der erfindungsgemäßen Drainagesonde 50. Dabei ist mit 52 der abführende Teil der Sonde bezeichnet, der in seiner Funktion einem herkömmlichen Drainageschlauch entspricht. Mit 54 ist das zuführende Lumen bzw. die zuführende Lichtung bezeichnet. Der Unterschied in der Lichtungsweite zwischen zuführendem und abführendem Teil sorgt dafür, daß der Unterdruck am pleuranahen Sondenende etwa dem am patientenfernen Ende mittels einer Unterdruckquelle appliziertem Sog gleicht und stellt den größeren Querschnittsanteil dem Materialabführenden Teil der Sonde zur Verfügung. Sowohl der Querschnitt gemäß Fig. 2a als auch die geschnittene Seitenansicht gemäß Fig. 2b zeigt einen stabilen Mandrin 56, mit dem die erfindungsgemäße Sonde in den Pleuraraum des Patienten eingebracht werden kann und der in das größere abführende Lumen 52 der Sonde 50 eingelegt wird. Mit 58 ist ein Griff des Mandrins 56 bezeichnet.

In der vergrößerten schematischen Skizze gemäß Fig. 3 ist am Ende der zuführenden Leitung (Zusatzleitung) 54 ein Anschluß 55 zur Ankopplung desjenigen Teils der Zusatzleitung erkennbar, der ein Zuspritzventil, einen Bakterienfilter, ein Sperrventil und eine Druckmeßvorrichtung aufnehmen kann. Die abführende Leitung kann ebenfalls einen Anschluß aufweisen, an dem ein weiterer Schlauchteil angekoppelt wird, der zum Flüssigkeitsabscheidegefäß führt.

In Fig. 4 ist eine bevorzugte Ausführungsform der erfindungsgemäßen Drainagevorrichtung dargestellt. In der zuführenden Zusatzleitung 54 ist, von der Patientenseite her gesehen, zunächst ein Zuspritzventil 60 und dann (stromaufwärts) ein Bakterienfilter 62 angeordnet. Innerhalb der Umrandung (Kasten 70) befindet sich der wiederverwendbare Teil der Vorrichtung. Der wiederverwendbare Teil 70 weist zwei Durchflußmeßfühler 74 und 78 im zuführenden Teil 54 bzw. abführenden Teil 52 des Drains 50, ein Sicherheits-Sperrventil 72 und optional ein Manometer 76 auf. Das Manometer 76 ist nicht zwingend notwendig, da es an sich auch in üblichen Unterdruckquellen vorhanden ist. Ferner ist ein elektronisches Meß-, Steuer- und Anzeigegerät 80 vorgesehen. Das Gerät 80 zeigt die Meßwerte und die sich aus ihnen ergebenden Rechengrößen, wie die Strömungsdifferenz zwischen Ab- und Zuleitung an, schließt bei Strömungsdifferenzumkehr, d. h. Einstrom größer als Ausstrom, das Sicherheits-Sperrventil 72 und sorgt bei intermittierendem Betrieb für den periodischen Verschluß des Ventils 72. Ferner zeigt es Störungen an und signalisiert Alarmzustände. Mit 82 ist der Luft- bzw. Spülgaseintritt der Zusatzleitung 54 bezeichnet, während der gestrichelte Teil mit dem Pfeil am stromabwärtigen Ende der abführenden Leitung zu einer Unterdruckquelle 84 führt.

Bei der Ausführung gemäß Fig. 5, die zu einer späteren Zuschaltung der Meßvorrichtungen geeignet ist, ist im zuführenden Schenkel (Zusatzleitung) 54 ein Manometer 90 vorgesehen, das zwischen dem Zuspritzventil 60 und dem Bakterienfilter 62 liegt, sowie stromaufwärts ein Belüftungsventil 92 und ein abnehmbarer Verschluß 94. Statt des Verschlusses 94 kann auch ein Sperrventil zur programmierten intermittierenden Gasdurchspülung aufgesetzt sein, wie vorstehend beschrieben. Bei der Erweiterung kann ferner neben dem Manometer 76 bei 96 ein Durchflußmeßgerät (Flowmeter) angeschlossen werden, ebenso kann auch zwischen dem Belüftungsventil 92 und dem Verschluß 94 bzw. dem

Sperrventil ein Durchflußmeßgerät geschaltet werden.

#### Patentansprüche

1. Drainagevorrichtung zum Absaugen von Fluiden aus einer Körperhöhle, insbesondere der Pleurahöhle, mit einem Drainageschlauch (84) zum Absaugen der Fluide und einer Einrichtung (82) zum Ausbilden eines Unterdrucks in der Körperhöhle (12), dadurch gekennzeichnet, daß eine Zusatzleitung (54) vorgesehen ist, deren Lumen am patientenseitigen Ende in Fluidverbindung mit dem Lumen des Drainageschlauches (52) steht.
2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Drainageschlauch (52) und die Zusatzleitung (54) miteinander verbunden und zumindest teilweise als doppelläufiger Schlauch oder doppelläufige Drainagesonde (50) ausgebildet sind.
3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß in der Zusatzleitung (54) ein Bakterienfilter (62) angeordnet ist.
4. Vorrichtung nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß in der Zusatzleitung (54) ein Durchflußmesser (74) angeordnet ist.
5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß in der Zusatzleitung (54) ein Sperrventil (72) angeordnet ist.
6. Vorrichtung nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß in der Zusatzleitung (54) ein Zuspritzventil (60) vorgesehen ist.
7. Vorrichtung nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß die Vorrichtung derart ausgebildet ist, daß die Differenz der Fluidströmungen in dem Drainageschlauch (52) und in der Zusatzleitung (54) meßbar ist.
8. Vorrichtung nach einem der Ansprüche 1 bis 7, gekennzeichnet durch eine Einrichtung (72) zum automatischen Sperren der Zusatzleitung (54), wenn die Strömung in der Zusatzleitung (54) höher ist als im Drainageschlauch (52).
9. Vorrichtung nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß die Zusatzleitung (54) intermittierend betreibbar ist.
10. Vorrichtung nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß die Zusatzleitung (54) verschließbar ist.
11. Vorrichtung nach Anspruch 10, dadurch gekennzeichnet, daß in der Zusatzleitung (54) vom patientenseitigen Ende her nacheinander das Zuspritzventil (60), ein Manometer (90), das Bakterienfilter (62) und ein Belüftungsventil (92) angeordnet sind.
12. Vorrichtung nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, daß der Leitungsquerschnitt des Drainageschlauches (52) größer ist als der Leitungsquerschnitt der Zusatzleitung (54).
13. Vorrichtung nach einem der Ansprüche 2 bis 12, dadurch gekennzeichnet, daß der Drainageschlauch (52) und die Zusatzleitung (54) in dem doppelläufigen Drain (50) coaxial ausgebildet sind.
14. Doppelläufiger Drain mit einem Drainageteil (52) und einer Zusatzleitung (54), die an einem Ende miteinander in Fluidverbindung stehen, insbesondere zur Verwendung in einer Drainagevorrichtung nach einem der Ansprüche 1 bis 13, gekennzeichnet durch Einrichtungen (74, 78, 80) zum Messen der Differenz zwischen der Fluidströmung in dem Drainageteil (52) und der Fluidströmung in der

Zusatzleitung (54).

Hierzu 4 Seite(n) Zeichnungen

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## Drainage apparatus and method of use

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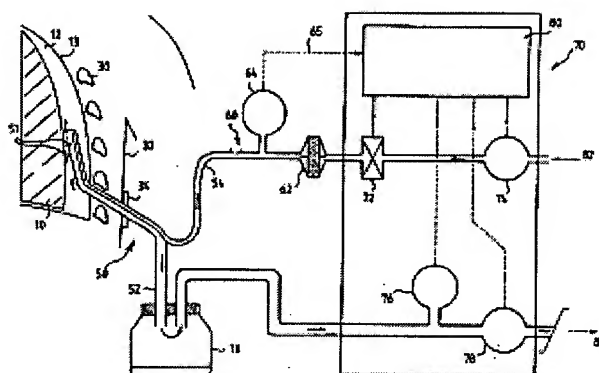
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PCT No. PCT/EP94/00613 Sec. 371 Date Sep. 1, 1995 Sec. 102(e) Date Sep. 1, 1995 PCT Filed Mar. 2, 1994 PCT Pub. No. WO94/20152 PCT Pub. Date Sep. 15, 1994 The invention concerns a drainage device for removing fluids by suction from body cavities, in particular from pleural cavity (12), the device having a drainage line (52) for removing the fluids by suction and a device (84) for creating an underpressure in the body cavity. The invention calls for an auxiliary line (54) whose channel at the patent end is in fluid contact with the channel of the drainage line (52), and for a gas to be supplied to the body cavity through the auxiliary line. The drainage device proposed enables troubles in drainage to be avoided and ensures that the drainage system is not obstructed.



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⑨ BUNDESREPUBLIK  
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DEUTSCHES  
PATENTAMT

⑫ **Gebrauchsmuster**  
⑩ **DE 295 04 378 U 1**

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**A61 M 1/04**

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⑤④ Elektronisch geregelte Niedervakuumpumpe für die Thorax- und Wunddrainage

DE 295 04 378 U 1

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Beschreibung:

- Niedervakuumpumpen zur Thorax- oder Wunddrainage üblicher Bauart bestehen aus einer schweren, batteriebetriebenen Saugeinheit. Die Vakuumstärke wird mechanisch über einen Druckregler, durch ein Ventil, das eine Undichtigkeit erzeugt, oder durch ein sogenanntes Wasserschloß erreicht.

Eine andere Bauart wird an eine zentrale Vakuumversorgungsanlage angeschlossen, die Saugstärke wird hier auch durch einen Regler und ein sogenanntes Wasserschloß reguliert. (DE 3908680A1, EP0402117A2)

Die erste Bauart macht es dem Patienten durch ihre Größe und ihr Gewicht fast unmöglich sich frei zu bewegen und fesselt ihn ans Bett.

Die zweite Bauart ist bedingt durch den Anschluß an die zentrale Vakuumversorgungsanlage oder Druckluftversorgungsanlage überhaupt nicht mobil einsetzbar.

Mit der Erfindung wird erreicht, daß ein Patient, der gesundheitlich in der Lage ist, sich frei zu bewegen, nicht mehr an das Bett gefesselt ist. Zumindest wird die Benutzung einer normalen Toilette ermöglicht. Auch die Entlassung des Patienten aus der Klinik und die Anwendung des Gerätes in Heimtherapie ist möglich.

Die Weiterbildung nach Schutzanspruch 2 ermöglicht durch den sparsamen Umgang mit der elektrischen Energie eine erhöhte Akku-Lebensdauer und eine exakt geregelte Vakuumstärke.

Durch das extrem niedrige Gewicht z. B. unter 500g und das kleine Volumen des Gerätes wird gegenüber herkömmlichen Geräten erreicht, daß der Patient sich auch ohne Hilfsperson beziehungsweise mit einem Fahrständer frei bewegen kann.

Die Schaltung des Ist-Soll-Tasters erlaubt es dem Pflegepersonal ohne zusätzliches Werkzeug den Sollwert der Vakuumstärke zu verändern, verhindert aber unbeabsichtigte Änderung durch den Patienten.

Durch die Auslösung eines optischen und akkustischen Alarms wird ständig die Wirksamkeit und Funktionsfähigkeit der Niedervakuumpumpe überwacht. Eine auftretende Undichtigkeit wird dem Pflegepersonal sofort gemeldet. Schon beim Anlegen des Drainagekatheters kann über die Anzeige der Vakuumstärke die Wirksamkeit der Drainage kontrolliert werden.

Das automatische Mitführen der Alarmgrenze erspart dem Pflegepersonal bei jeder Änderung der Soll-Vakuumstärke auch die Alarmgrenze neu einzustellen.

Durch das Umschalten von Ist-Wert der Vakuumstärke auf den Sollwert bei Betätigen der Ist-Soll-Taste wird eine zweite Anzeige eingespart.

Die Speicherung des zuletzt eingestellten Sollwertes der Vakuumstärke erspart es dem Pflegepersonal, bei jedem Einschalten des Gerätes den Sollwert neu einzustellen.

Ein Ausführungsbeispiel der Erfindung wird anhand Fig. 1 erläutert.

Ein Elektromotor (17) betreibt eine Miniatur-Vakuumpumpe (16), die am Unterdruckanschluß über einen Filter (13) und eine Sekretflasche (14) mit dem Drainagekatheter (15) verbunden ist, erzeugt in diesem ein Vakuum.

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Der im Sollwertspeicher (8) durch den Druckeinstelltaster Ab (9) und den Druckeinstelltaster Auf (10) eingestellte Wert, der durch Betätigung des Soll-Ist-Tasters (20) auf der Druckanzeige (11) abgelesen werden kann, wird vom Regler (19) ständig mit dem vom Drucksensor (12) ermittelten Istwert verglichen. Regler (19) und automatischer Umschalter (18) steuern den Elektromotor (17) in der Weise, daß Soll- und Istwert der Vakuumstärke übereinstimmen.

Die Druck-Überwachung (6) erzeugt mit dem akustischen Signalgeber (5) ein akustisches, und der Warn-Leuchtdiode Druck (7) ein optisches Warnsignal, falls der Istwert der Vakuumstärke die Alarmgrenze unterschreitet.

(zum Beispiel beim Auftreten einer Undichtigkeit)

Dabei wird die Alarmgrenze je nach Einstellung des Soll-Wertes automatisch geändert, sodaß die Differenz zwischen Sollwert und Alarmgrenze konstant bleibt.

Die Stromversorgung (21) wird wahlweise über einen austauschbaren Akku (2) oder über ein Netzteil (1) versorgt.

Die Akku-Überwachung (3) erzeugt mit dem akustischen Signalgeber (5) ein akustisches und der Warn-Leuchtdiode Akku (4) ein optisches Warnsignal, falls die Versorgungsspannung nicht mehr ausreicht, und der Akku (2) gewechselt werden muß.

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Teile-Liste

1. Netzteil
2. Akku
3. Akku-Überwachung
4. Warn-Leuchtdiode Akku
5. Akustischer Signalgeber
6. Druck-Überwachung
7. Warn-Leuchtdiode Druck
8. Sollwertspeicher
9. Druckeinstelltaster Ab
10. Druckeinstelltaster Auf
11. Druckanzeige
12. Drucksensor
13. Filter
14. Sekretflasche
15. Drainagekatheter
16. Miniatur-Vakuumpumpe
17. Elektromotor
18. Automatischer Umschalter
19. Regler
20. Ist-Soll-Taste
21. Stromversorgung

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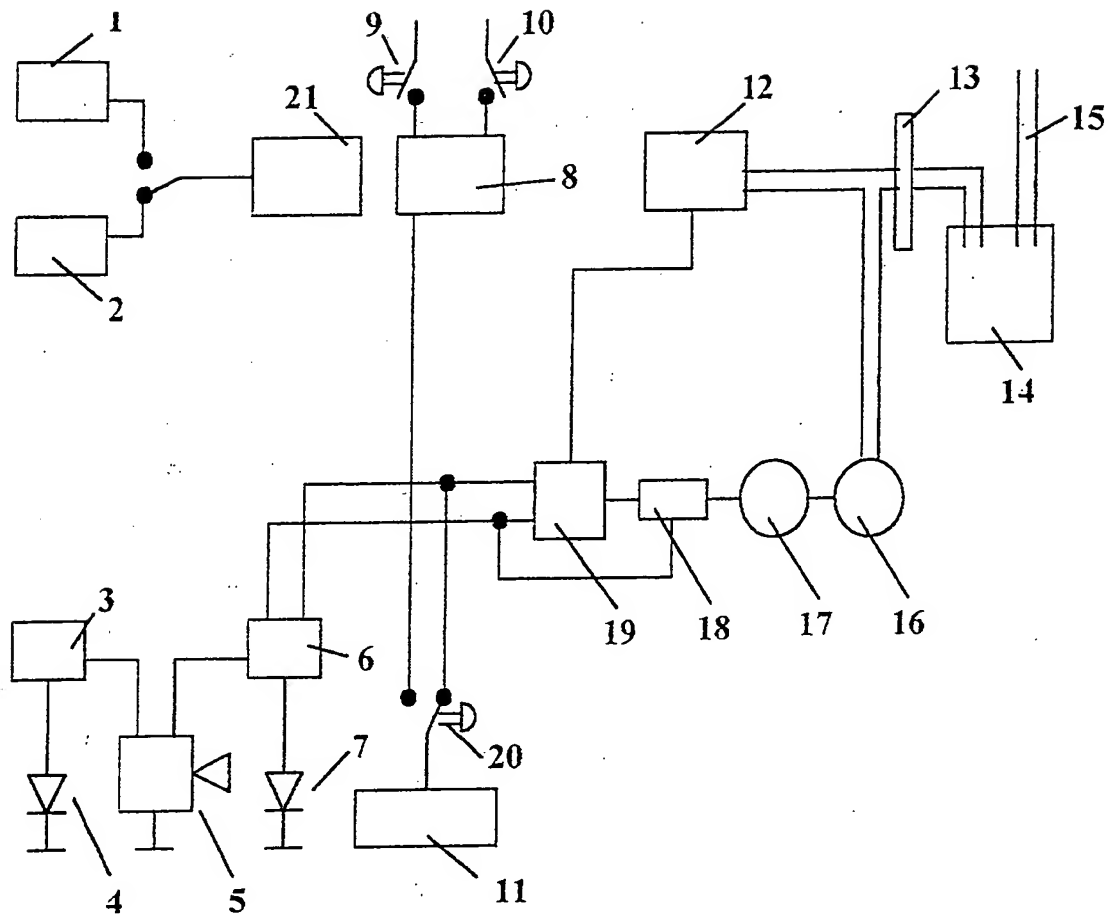
**Schutzansprüche:**

1. Elektronisch geregelte Niedervakuumpumpe zur Thorax- oder Wunddrainage, dadurch gekennzeichnet, daß der Unterdruck über eine mit Netzteil (1) oder mit austauschbarem Akku (2) betriebene Miniatur-Vakuumpumpe (16) erzeugt wird, und somit mobil einsetzbar ist.
2. Elektronisch geregelte Niedervakuumpumpe nach Schutzanspruch 1, dadurch gekennzeichnet, daß die eingestellte Vakuumstärke direkt von der Miniatur-Vakuumpumpe, die durch einen Drucksensor(12), einen Regler(19) und einen automatischen Umschalter (18) geregelt wird, erzeugt wird, und damit eine lange Akkumulator-Lebensdauer und ein exakt geregeltes Vakuum gewährleistet.
3. Elektronisch geregelte Niedervakuumpumpe nach Schutzanspruch 1, dadurch gekennzeichnet, daß die Einstellung der Vakuumstärke über zwei Druckeinstelltaster (9 und 10) an der Vorderseite des Gerätes eingestellt wird, deren Betätigung nur dann eine Wirkung hat, wenn zusätzlich zu einer dieser Tasten die Ist-Soll-Taste (20) an der Geräterückseite betätigt wird.
4. Elektronisch geregelte Niedervakuumpumpe nach Schutzanspruch 1, dadurch gekennzeichnet, daß bei einer Unterschreitung des gemessenen Ist-Werts der Vakuumstärke unter die Alarmgrenze ein optischer und akustischer Alarm ausgelöst wird.
5. Elektronisch geregelte Niedervakuumpumpe nach Schutzanspruch 1, dadurch gekennzeichnet, daß bei einer Änderung des Druck-Sollwertes die Alarmgrenze automatisch nachgeführt wird, so daß ein fest eingestellter Differenzwert zwischen Sollwert und Alarmgrenze eingehalten wird.
6. Elektronisch geregelte Niedervakuumpumpe nach Schutzanspruch 1, dadurch gekennzeichnet, daß durch Betätigen der Ist-Soll-Taste(20) die Anzeige vom Ist-Wert auf den Sollwert umschaltet.
7. Elektronisch geregelte Niedervakuumpumpe nach Schutzanspruch 1, dadurch gekennzeichnet, daß der Sollwert der Vakuumstärke gespeichert wird, damit ist eine Neueinstellung des Gerätes nach jedem Einschalten unnötig.

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Fig. 1



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# EUROPEAN PATENT APPLICATION

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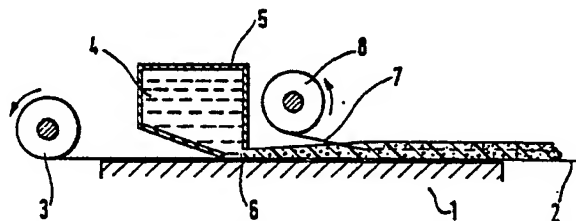
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54 **Medical-surgical dressing and a process for the production thereof.**

57 A medical-surgical dressing comprising a reinforced sheet of silicone elastomer foam having a thickness not exceeding 10 millimetres, one of the surfaces of the sheet having a surface layer of open cell foam and the other surface having a substantially non-cellular surface skin. The dressing may be manufactured by a process comprising depositing a liquid foamable silicone composition (4) on an absorbent surface (2), incorporating a reinforcing material (6), allowing the composition to foam and set to an elastomer and thereafter separating the foam sheet from the substrate.

The dressings are useful e.g. for the treatment of wounds, burns and as liners for plaster casts.



MEDICAL-SURGICAL DRESSING AND A PROCESS  
FOR THE PRODUCTION THEREOF

This invention relates to a surgical or medical dressing suitable for use in the treatment of burns and other injury, and also relates to a process for the production of such a dressing.

5       The treatment of burns and wounds has historically involved the application of sterile fibrous dressings such as gauze and lint, with or without the conjoint use of antiseptic or curative substances. Such materials tend to stick to the surface being treated or leave  
10       fibres in the wound. More recent developments have involved the application of synthetic films and sponges to the injury. For example U.S. Patent 3 439 676 describes a wound dressing which is a band of self-adhering silicone elastomer impregnated with a  
15       medicament. However, such a dressing is non-absorbent with regard to the exudations normally present.

U.S. Patent 3 648 692 describes a surgical dressing comprising a facing layer of neutral thrombogenic reticulated open cell foam material and a mutually  
20       secured co-extensive, gas permeable, microporous backing. The preferred foam material is stated therein to be polyurethane foam and the backing may be of, for example polypropylene, teflon or silicone rubber. However, the manufacture of such a dressing requires that the backing  
25       and foam layers be preformed and then subsequently brought together with an adhesive in a laminating operation.

According to the present invention there is provided a medical-surgical dressing comprising a  
30       reinforced sheet of silicone elastomeric foam having a

thickness of not greater than 10 millimetres, one surface of the said sheet having a surface layer of open cell foam and the other surface having a substantially non-cellular surface skin.

5           The dressings of this invention comprise sheets of silicone elastomeric foam wherein the broad surface intended for contact with the body has an open cell foam structure and the outer surface comprises a substantially non-cellular skin. In order to improve its resistance  
10 to tearing or other damage during use the foam dressing is reinforced with a suitable fibrous or weblike material, for example nylon or polyester net. The dressings have a thickness not greater than 10mm and preferably have a thickness of from about 3 to about 6mm.

15           One method of producing dressings according to this invention involves depositing a foamable silicone elastomer composition on a substrate and allowing it to foam whereby a substantially non-cellular, continuous skin forms at the exposed surface. During foaming a  
20 reinforcing web may be embedded in the foam. When cured the upper portion of the foam block may be cut away to provide a sheet having the desired reinforcement and surface characteristics. Such a method, however, poses several problems. For example, it is difficult to cut  
25 accurately thin sections of an elastomeric foam. The method is also wasteful since only the upper portion of the foam can be used to provide a sheet with the desired surfaces.

30           We have discovered that it is possible to obtain the foam dressings of this invention by a novel method which avoids the disadvantages associated with the above described procedure. Accordingly this invention also includes a process for the manufacture of a medical-

surgical dressing which comprises applying a layer of a liquid foamable or foaming silicone elastomer composition to a substrate having a surface which is an absorbent for the liquid composition, adding a reinforcing material to the foamable or foaming composition such that it becomes embedded therein, allowing the mixture to foam or continue foaming and to set to an at least partially cured silicone elastomer foam and thereafter separating the foam layer from the substrate.

10 In the performance of the process of this invention any liquid foam-forming silicone elastomer composition may be employed. The preferred compositions for use according to this invention are those which comprise a polydiorganosiloxane having hydroxyl groups, a siloxane  
15 having silicon-bonded hydrogen atoms, a curing catalyst and a hydroxylated compound. They are normally made available as a two package product. When the contents of the packages are mixed in the appropriate proportions the mixture foams and subsequently sets to an  
20 elastomeric sponge. Compositions of this type are described in, for example U.K. Patents Nos. 798 667, 867 619, 1 064 462 and 1 543 215. Foam-forming compositions comprising organopolysiloxanes having silicon-bonded unsaturated groups, organosilicon  
25 compounds having silicon-bonded hydrogen atoms and an addition catalyst e.g. chloroplatinic acid may also be employed. Such compositions are described in, for example, U.K. Patents 1 522 637 and 1 542 657. Desirably the composition will be free of additives which may  
30 impart irritant or toxic properties to the dressing, especially when the dressing is to be employed in direct contact with the body for the treatment of open wounds or burns.

The substrate receiving the liquid foam composition should be sufficiently porous to be absorbent with regard to the composition. A preferred substrate material is a non-glazed paper which permits slight penetration of the liquid foam composition into its porous surface.

Fabrication of the dressing according to the novel process of this invention is conveniently carried out by preparing the liquid foamable composition and applying it while still in the flowable state to the substrate.

Depending on the rate of the chemical reaction involved the composition may at this stage be a liquid or may have already commenced expansion into a foam. Application of the composition may be carried out employing any suitable means, for example from a hopper having a lower transverse aperture or by way of a traversing dispensing nozzle which may be associated with a mixing head. The depth of the resulting foam appropriate to the desired thickness of the dressing can be controlled by the amount of foamable liquid employed and/or by the use of a scraper blade or an equivalent depth controlling device. A preferred method of depth/thickness control in the process of this invention comprises passing the substrate carrying the foamable or foaming composition beneath a slowly rotating roller positioned horizontally and transversely with respect to the direction of motion of the substrate. Any build up of cured or partially cured foam composition on the roller surface which may occur during operation may be readily removed therefrom by means of a scraper blade or similar device.

The process may be carried out batchwise or, more preferably, can also be performed as a continuous or semi-continuous operation. Thus for example the foamable or foaming composition may be poured into a stationary

receptacle or on to the moving substrate which is supplied from a roll or other source and thus itself forms, or is supported by, a conveyor belt.

Prior to the curing of the foam into a solid elastomer it is necessary to embed therein a suitable reinforcing material. This can be conveniently accomplished by placing a sheet of reinforcing material on the surface of the still liquid foamable or foaming composition after pouring and allowing or causing it to penetrate the composition to the desired depth. The actual depth of penetration of the reinforcing material is not critical provided that the material does not prevent the attainment of the desired skin-like or porous configurations of the respective surfaces of the dressing. In order to permit the ready penetration of the reinforcing material according to this technique the material should be sufficiently perforate or porous to permit flow-through of the foamable or foaming composition. A preferred reinforcing material is a textile net fabric, particularly of synthetic fibre, for example nylon, polyester, polypropylene or acrylic fibre.

Depending on the type of foam forming composition employed the foam sheet may be allowed to cure to an elastomeric solid at normal ambient temperatures or it may be desirable or necessary to hasten the cure by the application of heat.

When the composition has cured to an elastomeric solid it is removed from the substrate. In some cases it may be possible to separate the foam and substrate by carefully pulling them apart. However, in order to avoid the possibility of tearing the sheet it is preferred that separation be facilitated by the use of a parting knife or similar cutting edge placed against the substrate.

Any cutting edge or blade will suffice provided it is sufficiently sharp to cut the foam away from the substrate.

Exemplary means for carrying out the process of this invention are shown in Figures 1 and 2 of the drawings hereof which are sectional views in side elevation. In Figure 1, a table or other rigid surface 1 supports a flexible absorbent substrate 2 which is drawn from a roll or other source 3. The foamable silicone elastomer composition 4 is applied to the surface of the substrate 2 from a hopper 5 having a transverse slot 6. A reinforcing material 7 is drawn from a roll 8 and embedded in the liquid foamable composition.

Figure 2 illustrates a modification of the means shown in Figure 1 wherein the hopper 5 is replaced by a dispensing head 10 which may be adapted to traverse the support transversely with respect to its direction of motion. A rotatable roller 11 is positioned above the substrate receiving the foamable composition and transversely with respect to the direction of motion thereof. If desired the roller may be provided with a scraper blade (not shown) which functions to remove from the roller any accretion of cured or partially cured elastomeric foam.

The foam sheet may be produced in the final desired configuration, for example in the form of a narrow bandage or broad sheet, or it may be cut to the desired size and shape after curing. If desired the dressing may be subjected to elevated temperatures to increase the degree of cure, remove volatile substances or to effect sterilisation. Sterilisation may also be achieved by chemical means, such as by exposure to ethylene oxide.

The dressing may also be washed in water if necessary to remove unwanted residues. If desired the dressing may be coated or impregnated with a medicament, for example an antiseptic, antibiotic or other substance for the control  
5 of infection.

Possible applications for the dressings of this invention include their use as wound and burn dressings, as swabs and as liners for location between plaster casts and the body.

10 The following example illustrates the invention.  
A composition containing a silanol end-stopped polydimethylsiloxane, having a viscosity of approximately 2000 cP at 25°C, a trimethylsilyl end-stopped methyl-  
15 hydrogen polysiloxane, a low molecular weight hydroxylated methyl siloxane, a diatomaceous earth and stannous octoate as catalyst was prepared by thoroughly mixing the components.

The liquid mixture was then pumped into a box resting in contact with a porous paper substrate having  
20 a width of about 25 cm and supported on a rigid horizontal surface. The forward wall of the box was cut so that a gap of approximately 2 mm existed between the lower edge of the wall and the substrate. The floor of the box adjacent to this edge was also cut away thus  
25 permitting the liquid foam composition to be drawn forward with the paper.

Foaming of the composition occurred shortly after deposition on the paper. At the commencement of foaming the paper was drawn forward. Simultaneously a nylon net  
30 fabric having a mesh size of approximately 2 mm was drawn from a roll situated above the foam and allowed to sink into the foam under a slight downward tension. The process was terminated after several metres of the paper

substrate had been drawn off and the foam-coated substrate allowed to stand for 30 minutes to ensure that cure had proceeded to a sufficient degree to produce an elastomeric solid. A large blade palette knife was then  
5 inserted at the interface between the substrate and the foam and employed to cut the foam from the paper.

The product was a flexible, reinforced elastomeric foam sheet having a thickness of about 5 mm. The upper surface of the sheet had a substantially continuous skin  
10 whilst the lower surface had a cellular structure. After washing to remove unreacted materials, and sterilisation the sheet was suitable for use as a medical-surgical dressing.

CLAIMS

1. A medical-surgical dressing comprising a reinforced sheet of silicone elastomeric foam having a thickness not greater than 10 millimetres, one surface of the said sheet having a surface layer of open cell foam and the other surface having a substantially non-cellular surface skin.
2. A medical-surgical dressing as claimed in Claim 1 wherein the reinforcement comprises a textile net fabric.
3. A process for the manufacture of a medical-surgical dressing which comprises applying a layer of a liquid foamable or foaming silicone elastomer composition to a substrate having a surface which is an absorbent for the liquid composition, adding a reinforcing material to the foamable or foaming composition such that it becomes embedded therein, allowing the mixture to foam or continue foaming and to set to an at least partially cured silicone elastomer foam and thereafter separating the foam layer from the substrate.
4. A process as claimed in Claim 3 wherein the absorbent substrate is a non-glazed paper.
5. A process as claimed in Claim 3 or Claim 4 wherein separation is effected by means of a cutting edge.
6. A process as claimed in any of Claims 3 to 5 wherein the separated foam sheet is subjected to a sterilisation treatment.

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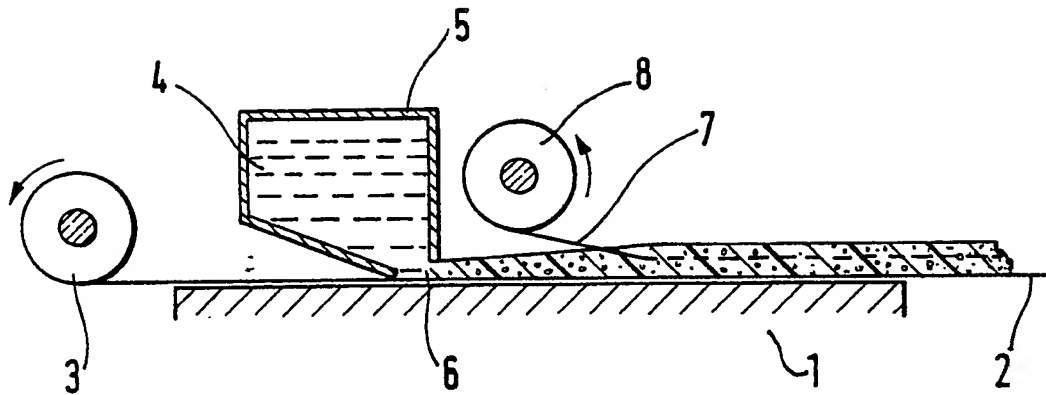


FIG. 1.

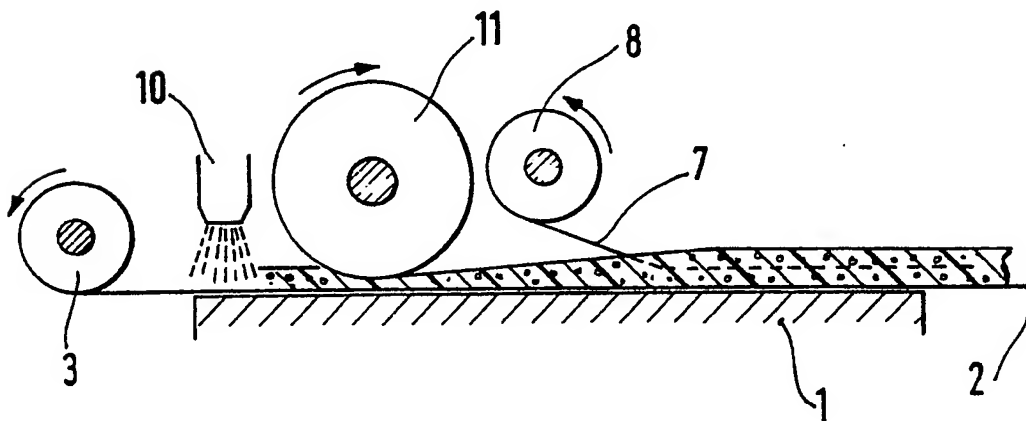


FIG. 2.



European Patent  
Office

# EUROPEAN SEARCH REPORT

0100148

Application number

EP 83 30 3679

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 7)
A	DE-A-3 032 092 (IPOS) * Claims 1,7 *	1	A 61 L 15/01 A 61 F 13/00
A	FR-A-2 370 479 (P.M. LOCK et al.) * Claims 1,2 *	1	
A	GB-A-1 124 121 (DOW CORNING) * Page 7, lines 59-64; claim 1 *	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 7)
			A 61 L 15/01
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 31-10-1983	Examiner PELTRE CHR.
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	